UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

Date: 01/04/12

SUBJECT: **Azoxystrobin**. Section 3 Petition For Uses On Tuberous and Corm Vegetables Subgroup 1C (Postharvest); Dragon Fruit; Wasabi; and Crop Group Expansions for Bulb Vegetables 3-07A and 3-07B; Caneberries 13-07A; Bushberries 13-07B; Small Fruit Vine Climbing 13-07F, Except Fuzzy Kiwifruit; Low Growing Berry 13-07G, Except Cranberry; Citrus Crop Group 10-10; Fruiting Vegetable Crop Group 8-10A and 8-10B; and Oilseed Crop Group 20. Summary of Analytical Chemistry and Residue Data.

PC Code: 128810
Decision No.: 447240

Petition No.: PP#1E7851
Risk Assessment Type: Single Chemical/Aggregate
TXR No.: NA
MRID No.: 48437101

DP Barcode: D390152
Registration Nos.: 100-1098, 100-1308, 100-1313, 100-1324, and 100-1178
Regulatory Action: Section 3 Registration
Case No.: NA

CAS No.: 131860-33-8
40 CFR: 180.507

FROM: Meheret Negussie, Chemist *Meheret Negussie*
Risk Assessment Branch III
Health Effects Division (7509P)

THROUGH: Leung Cheng, Senior Chemist *Leung Cheng*
Risk Assessment Branch III
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TO: Barbara Madden, RM#05
Minor Use, Inerts and Emergency Response Branch (MUIERB)
Registration Division (7505P)

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Executive Summary

Azoxystrobin is a broad-spectrum fungicide and belongs to a class of pesticidal compounds called β-methoxyacrylates, which are derived from the naturally occurring strobilurins (Group 11 fungicides). The biochemical mode of action is inhibition of electron transport. The fungicide is currently registered for use on a variety of field, vegetable, fruit, and nut crops as well as on ornamental plants and turf. End-use products of azoxystrobin are typically formulated as water dispersible granular (WDG) and suspension concentrate (SC; previously referenced as flowable concentrate) formulations. These products may be applied as in-furrow at planting or postemergence foliar applications using ground or aerial equipment at maximum seasonal rates of 0.40-2.0 lb ai/A. Azoxystrobin is also registered for seed treatment of many food/feed crops as well as for postharvest uses on bananas/plantains and citrus fruit. For the proposed postharvest use of the tuberous and corm vegetables subgroup 1C, a three-way mixture of azoxystrobin, difenoconazole, and fludioxonil is used. The three-way mixture provides broad-spectrum disease control and built-in resistance management. The use is needed to control silver scurf and fusarium rot during storage.

Under PP#1E7851, Interregional Research Project No. 4 (IR-4), on behalf of the Agricultural Experiment Stations, is requesting establishment of tolerances for the combined residues of the fungicide azoxystrobin, [methyl(*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and the *Z*-isomer of azoxystrobin, [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] in or on the following commodities :

Onion, bulb, subgroup 3-07A .... 1.0 ppm
Onion, green, subgroup 3-07B .... 7.5 ppm
Vegetable, fruiting, subgroup 8-10A .... 0.2 ppm
Vegetable, fruiting, subgroup 8-10B .... 2.0 ppm
Fruit, citrus, group 10-10 .... 10.0 ppm
Caneberry subgroup 13-07A .... 5.0 ppm
Bushberry subgroup 13-07B .... 3.0 ppm
Small fruit vine climbing, except fuzzy kiwifruit subgroup 13-07F .... 1.0 ppm
Low growing berry subgroup 13-07G, except cranberry ... 10.0 ppm
Rapeseed subgroup 20A .... 1.0 ppm
Sunflower subgroup 20B .... 0.5 ppm
Cottonseed subgroup 20C .... 0.6 ppm
Wasabi .... 50 ppm
Dragon-fruit .... 2.0 ppm

Concurrently, IR-4 wishes to amend (increase) the tolerance for the following crop subgroup as follows:

Vegetable, tuberous and corm, subgroup 1C .... 6.0 ppm

In addition, IR-4 requests removal of the established tolerances for the following commodities:

Potato	0.03 ppm
Onion, bulb	1.0 ppm
Onion, green	7.5 ppm
Vegetable, fruiting, group 8, except tomato	2.0 ppm
Tomato	0.2 ppm
Fruit, citrus, group 10	10.0 ppm
Caneberry subgroup 13-A	5.0 ppm
Bushberry subgroup 13-B	3.0 ppm
Grape	1.0 ppm
Strawberry	10.0 ppm
Juneberry	3.0 ppm
Lingonberry	3.0 ppm
Salal	3.0 ppm
Cotton, undelinted seed	0.6 ppm
Canola, seed	1.0 ppm
Sunflower, seed	0.5 ppm
Crambe, seed	0.5 ppm
Flax, seed	0.5 ppm
Rapeseed, seed	0.5 ppm
Rapeseed, Indian	0.5 ppm
Mustard, field, seed	0.5 ppm
Mustard, Indian, seed	0.5 ppm
Safflower, seed	0.5 ppm

Under PP#1E7851, IR-4, on behalf of the Agricultural Experiment Stations, is requesting use of azoxystrobin, difenoconazole, or the three-way mixture of azoxystrobin + difenoconazole + fludioxonil on tuberous and corm vegetables subgroup 1C as a postharvest treatment. Syngenta Crop Protection, Inc. (Syngenta) submitted residue data for difenoconazole, azoxystrobin, and fludioxonil on potatoes following postharvest treatment. The subject review addresses the adequacy of the magnitude of the residues of azoxystrobin and the *Z*-isomer (R230310) only; difenoconazole and fludioxonil results are reported in separate DERs.

In addition, Syngenta has requested amendment of the product label for Abound® Flowable Fungicide (EPA Reg. No. 100-1098), an SC formulation containing 22.9% ai (2.08 lb ai/gal) azoxystrobin, to add uses on tuberous and corm vegetables subgroup 1C as a postharvest treatment, dragon fruit, and wasabi. The petitioner has also requested amendment of the labels for Abound® Flowable Fungicide (EPA Reg. No. 100-1098), Quilt® (EPA Reg. No. 100-1178), Graduate A+™ (EPA Reg. No. 100-1308), Quadris Top™ (EPA Reg. No. 100-1313), Quilt Xcel™ (EPA Reg. No. 100-1324), and azoxystrobin dry technical manufacturing use concentrate (EPA Reg. No. 100-1120) to incorporate the crop group/subgroup or representative commodity expansions.

Azoxystrobin tolerances have been established in 40 CFR §180.507. Tolerances for crop commodities are listed in 40 CFR §180.507(a)(1) and are expressed in terms of residues of the fungicide azoxystrobin and the *Z*-isomer of azoxystrobin. Tolerances are currently established for azoxystrobin in/on various plant commodities at levels ranging from 0.01 ppm in/on pecans and to 420 ppm in/on aspirated grain fractions.

Tolerances for livestock commodities are listed in 40 CFR §180.507(a)(2) and are expressed in terms of residues of azoxystrobin and its *Z*-isomer; the *Z*-isomer should be removed from the tolerance expression. The established tolerances for livestock commodities range from 0.006 ppm for milk to 0.07 ppm for the meat byproducts of cattle, goat, horse, and sheep; no tolerances are currently established for poultry commodities.

The existing established tolerances on onion, bulb (1.0 ppm) (for onion, bulb subgroup 3-07A); onion, green (7.5 ppm) (for onion, bulb subgroup 3-07B); tomato (0.2 ppm) (for tomato subgroup 8-10A); vegetable, fruiting, group 8, except tomato (2.0 ppm) (for pepper/eggplant subgroup 8-10B); fruit, citrus, group 10 (10.0 ppm) (for fruit, citrus, group 10-10); caneberry subgroup 13A (5 ppm) (for caneberry subgroup 13-07A); bushberry subgroup 13-07B (3.0 ppm) and juneberry, lingonberry, and salal (3.0 ppm) (for bushberry subgroup 13-07B); grape (1.0 ppm) (for fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F); strawberry (10.0 ppm) (for berry, low growing, subgroup 13-07G, except cranberry); canola seed (1.0 ppm) (for rapeseed subgroup 20A); safflower, seed and sunflower, seed (0.5 ppm) (for sunflower subgroup 20B); and cotton, undelinted seed (0.6 ppm) (for cottonseed subgroup 20C) were used to establish the proposed tolerances. The proposed tolerance changes are a result of revisions in the crop groups and are conversions from existing groups/subgroups or representative commodities. The proposed tolerances for the dragon fruit and wasabi are extrapolated from existing azoxystrobin tolerances on mango (2.0 ppm) and the herb subgroup 19A, fresh leaves (50 ppm), respectively. HED concludes that the available data on these commodities and/or crop groups/subgroups are adequate to establish the tolerances on the proposed crop groups/subgroups. No new residue data are submitted or are needed for these changes.

The nature of the residue in plants, rotational crops, and livestock is adequately understood. Acceptable metabolism studies have been conducted on primary crops of grapes, peanuts, and wheat as well as on representative rotational crops. Acceptable metabolism studies on goats and laying hens are also available. The residues of concern in/on primary and rotational crop commodities, for tolerance expression and risk assessment purposes, are azoxystrobin and its *Z*-isomer. The residue of concern in livestock is parent azoxystrobin only.

Adequate residue analytical methods are available for tolerance enforcement: a gas chromatography method with nitrogen-phosphorus detection (GC/NPD), RAM 243/04, for the analysis of crop commodities for residues of azoxystrobin and its *Z*-isomer; and a GC/NPD method, RAM 255/01, for analysis of livestock commodities for residues of azoxystrobin.

For analysis of samples from the potato postharvest field trials associated with the current petition, a high performance liquid chromatography method with tandem mass spectrometric detection (LC/MS/MS), Method 305/03, was used as the data-collection method. RAM 305/03 was adequately validated at fortification levels ranging from 0.01-10 ppm on potato tubers, potato flakes, and potato chips.

There is an existing use for azoxystrobin on potatoes and corm vegetables subgroup 1C with an established tolerance of 0.03 ppm. Acceptable field trial studies have been submitted to support the requested tolerance increase of the established tolerance on tuberous and corm vegetables subgroup 1C from 0.03 ppm to 6.0 ppm; the studies are supported by adequate existing storage stability data. The Organization for Economic Cooperation and Development (OECD) statistical calculation procedures were used to determine appropriate tolerance levels. Based on the available data, the proposed tolerance for vegetable, tuberous and corm, subgroup 1C must be revised to reflect the appropriate tolerance level estimated using the OECD statistical calculation procedures. HED recommends a tolerance of 8.0 ppm for *vegetable, tuberous and corm, subgroup 1C.*

The submitted postharvest potato processing study is acceptable. Residues of azoxystrobin did not concentrate in potato cakes, potato chips, and potato peel following processing of the raw agricultural commodity (RAC) (pre-processed tubers) with quantifiable residues. No tolerances are required for these processed commodities.

Adequate cattle and poultry feeding studies are available to support the proposed uses. No changes to the existing livestock commodity tolerances are needed.

Adequate field rotational crop data are available to support the existing rotational crop restrictions on the product labels: a 12-month plantback interval has been established for buckwheat, millet, oats, and rye; and a 36-day plantback interval has been established for the leafy vegetables (except *Brassica*) group, the *Brassica* leafy greens subgroup, the root vegetables subgroup, the tuberous and corm vegetables subgroup, and the leaves of root and tuber vegetables group.

There are Canadian and Codex MRLs for residues of azoxystrobin and its (Z)-isomer for most of the requested crops. The Codex MRLs (JMPR Report 2008) are based on US field trials, except for subgroup 8-10A and 8-10B which were conducted in Europe. Even though the Codex MRLs are based on US field trials, there is a slight difference between MRLs of Codex/US due in part to the difference in the residue definition. The US residue definition includes both the predominant E isomer and the minor Z isomer. The Codex residue definition includes only the E isomer. The difference in Codex and US MRL estimates, based on the same data set, is based on the JMPR rounding procedures and the tendency to increase the estimate for small data sets.

The US and Codex MRLs are in harmony for subgroup 13-07A, strawberries, and sunflower seeds. The US and Codex MRLs are not in harmony for subgroup 13-07G; dragon-fruit (mango); onion, bulb dry and green; vegetable subgroup 8-10A; tuberous and corm vegetables subgroup 1C and wasabi (herbs, fresh and dry).

HED recommends increasing the US tolerances for bushberry, subgroup 13-07B, cottonseed, citrus fruit, 10-10, fruit vine climbing 13-07F [grape], and pepper/eggplant 8-10B to harmonize with Codex.

The US and Canadian MRLs are in harmony on all proposed crops, except subgroup 13-07F, 13-07G, and cotton seed. There are no Canadian tolerances on cottonseed. Canadian tolerances were not established as subgroups for 13-07F and 13-07G and were established on grapes (3 ppm) and lowbush blueberries and lingonberries (subgroup 13-07B) at 3 ppm; US tolerances were established at 1 ppm for 13-07F and at 10 ppm for 13-07G. The current post-harvest use of the tuberous and corm vegetables subgroup 1C, recommends increasing the US tolerance for vegetable tuberous and corm, subgroup 1C to 8 ppm, which is in agreement with the proposed Canadian MRL.

Analytical reference standards for azoxystrobin and its *Z*-isomer are currently available at the EPA National Pesticide Standards Repository.

Regulatory Recommendations and Residue Chemistry Deficiencies

Pending submission of a revised Sections B and F, there are no residue chemistry issues that will preclude establishment of permanent tolerances for azoxystrobin in/on the following crops or crop groups/subgroups:

Onion, bulb, subgroup 3-07A .... 1.0 ppm
Onion, green, subgroup 3-07B .... 7.5 ppm
Tomato subgroup 8-10A .... 0.2 ppm
Pepper/eggplant subgroup 8-10B .... 3.0 ppm
Fruit, citrus, group 10-10 .... 15.0 ppm
Caneberry subgroup 13-07A .... 5.0 ppm
Bushberry subgroup 13-07B .... 5.0 ppm
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F .... 2.0 ppm
Berry, low growing, subgroup 13-07G, except cranberry..10.0 ppm
Rapeseed subgroup 20A.. 1.0 ppm
Sunflower subgroup 20B .... 0.5 ppm
Cottonseed subgroup 20C .... 0.7 ppm
Wasabi, fresh.. 50 ppm
Wasabi, dry .... 260 ppm
Dragon-fruit .... 2.0 ppm
Vegetable, tuberous and corm, subgroup 1C .... 8.0 ppm

Note to RM: In conjunction with establishment of the above tolerances, the existing tolerances for potato; onion, bulb; onion, green; vegetable, fruiting, group 8, except tomato; okra; tomato; fruit, citrus, group 10; caneberry subgroup 13A; bushberry subgroup 13B; grape; strawberry; juneberry; lingonberry; salal; cotton, undelinted seed; canola, seed; sunflower, seed; crambe, seed; flax, seed; rapeseed, seed; rapeseed, Indian; mustard, field, seed; mustard, Indian, seed; mustard, seed; and safflower, seed need to be removed from 40 CFR §180.507(a).

Note to RM: The e-CFR includes the *Z*-isomer in the tolerance expression for livestock. The *Z*-isomer should be removed from the tolerance expression for livestock.

A human health risk assessment is forthcoming.

Residue Chemistry Deficiencies

860.1200 Directions for Use

- The proposed use directions for post-harvest potatoes should be revised to indicate post-harvest use on tuberous and corm vegetables, subgroup 1C rather than on potatoes only.

860.1550 Proposed Tolerances

- A revised Section F must be submitted to reflect the recommended tolerance for vegetable, tuberous and corm, subgroup 1C at 8.0 ppm and the correct commodity definitions as shown in Table 9.

- A revised Section F must be submitted to propose a tolerance for wasabi, dry at 260 ppm.

Background

The chemical structure and nomenclature of azoxystrobin and its *Z*-isomer, and the physicochemical properties of the technical grade of azoxystrobin are presented in Tables 1 and 2, respectively.

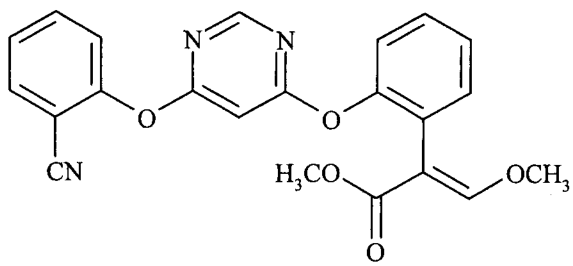
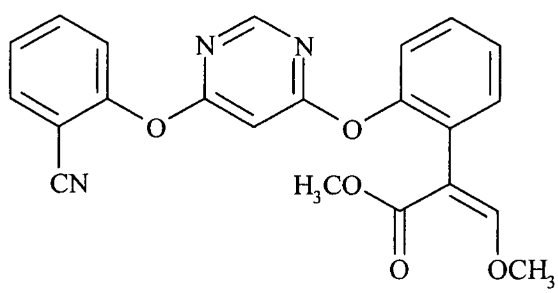
Table 1.	**Azoxystrobin Nomenclature.**
Compound	
Common name	Azoxystrobin
Company experimental name	ICIA5504 (Zeneca), R215504 (Syngenta)
IUPAC name	methyl (*E*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
CAS name	methyl (α*E*)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-α-(methoxymethylene)-benzeneacetate
CAS registry number	131860-33-8
End-use products (EP)	Abound® Flowable Fungicide (EPA Reg. No. 100-1098); Quilt® (EPA Reg. No. 100-1178), Graduate A+™ (EPA Reg. No. 100-1308), Quadris Top™ (EPA Reg. No. 100-1313), and Quilt Xcel™ (EPA Reg. No. 100-1324)
Regulated metabolite, Z-isomer	
Common name	Azoxystrobin, *Z*-isomer
Chemical name	methyl (*Z*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate

Table 2. Physicochemical Properties of Technical Grade Azoxystrobin.		
Parameter	Value	Reference
Melting point/range	114-116°C	DP#s 218318 and 218448, 3/19/96, J. Garbus
pH	6.4	
Density	1.25 g/cm^3	
Water solubility (20°C)	pH 5.2 6.7 mg/L pH 7.0 6.7 mg/L pH 9.2 5.9 mg/L	
Solvent solubility (20°C)	Hexane 0.057 mg/L Octanol 1.4 mg/L Methanol 20 mg/L Toluene 55 mg/L Acetone 86 mg/L Ethyl Acetate 130 mg/L Acetonitrile 340 mg/L Dichloromethane 400 mg/L	
Vapor pressure (20°C)	1.1×10^{-13} kPa (8.2×10^{-13} mm Hg)	
Dissociation constant, pK_a	Not dissociable	
Octanol/water partition coefficient, Log(K_{OW})	log P_{OW} = 2.5	
UV/visible absorption spectrum	Not available	

860.1200 Directions for Use

In Section B of the petition, IR-4 submitted amended labels for Abound® Flowable Fungicide (EPA Reg. No. 100-1098), to add new uses on potatoes (post-harvest), dragon fruit, wasabi, and crop group expansions. The petitioner has also requested amendment of the labels for Quilt® (EPA Reg. No. 100-1178), Graduate A+™ (EPA Reg. No. 100-1308), Quadris Top™ (EPA Reg. No. 100-1313), and Quilt Xcel™ (EPA Reg. No. 100-1324) to reflect the revision/expansion of the crop groups.

Table 3. Summary of Directions for Use of Azoxystrobin.						
Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	App. Rate (lb ai/A)	Max. No. App. / Season	Max. Seasonal App. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Potatoes (Post Harvest)						
In-line aqueous spray application	2.08 lb ai/gal SC [100-1098]	0.6 fl. oz./ton of tubers 0.0098 lb ai/2000 pound potatoes	1	N/A	N/A	Ensure proper coverage of the tubers. Tubers should be tumbling as they are treated. Mix the fungicide solution in an appropriate amount of water for the crop being treated. Use a T-jet, CDA, or similar application system. Must be used in tank mixture with difenoconazole and

Table 3. Summary of Directions for Use of Azoxystrobin.

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	App. Rate (lb ai/A)	Max. No. App. / Season	Max. Seasonal App. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
						fludioxonil. Do not make more than one postharvest application to tubers. Ensure the Abound solution remains in suspension by using agitation.
Herbs & Spices (except black pepper) Crop Group 19 (Existing), **Wasabi** (proposed)						
Begin making applications at the onset of disease development by ground. For Wasabi- Apply by ground or through irrigation system (chemigation)	Abound ® Fungicide [100-1098]	0.10-0.25	N/S	1.5	0	Applications should continue throughout the season on 7-day intervals following the resistance management guidelines. Adjuvant may be added at specified rates. Use a minimum of 30 gallons of water per acre.
Acerola, Atemoya, Avocado, Biriba, Canistel, Cherimoya, Custard apple, **Dragon Fruit (proposed)**; Feijoa, Guava, Ilama, Jaboticaba, Jackfruit, Longan, Loquat, Lychee, Mango, Papaya, Passionfruit, Pawpaw, Persimmon, Pulasan, Rambutan, Sapodilla, Sapote black, Sapote, mamey, Sapote white, Soursop, Star apple, Starfruit, Sugar apple, Spanish lime, and Tamarind (Existing)						
Apply by ground, air, or chemigation prior to disease development	Abound ® Fungicide [100-1098]	0.10-0.25	N/S	1.5	0	Applications should continue throughout the season on 7-10-day interval following the resistance management guidelines. Adjuvant may be added at specified rates.

Resistance Management: The label for Abound® (EPA Reg. No. 100-1098) specifies that the product should be integrated into an overall disease and pest management strategy and that for resistance management, no more than two foliar applications of Abound® Flowable Fungicide (one application for bulb vegetables, peppers and other fruiting vegetables) or other Group 11 fungicides should be made before alternating with a fungicide having a different mode of action (not in Group 11).

The following plantback intervals (PBIs) have been established: 12 months for buckwheat, millet, oats, and rye; 36 days for leafy vegetables (except *Brassica*) group, *Brassica* leafy greens subgroup, root vegetables subgroup, tuberous and corm vegetable subgroup, and leaves of root and tuber vegetables group; and 0 days for all other crops.

Conclusions: The label directions are adequate to allow evaluation of the residue data relative to the proposed uses. The proposed supplemental label for dragon-fruit and wasabi is adequate. The proposed use directions for post-harvest potatoes should be revised to indicate post-harvest use on tuberous and corm vegetables, subgroup 1C rather than on potatoes only.

860.1300 Nature of the Residue - Plants

PP#5F4541; DP#s 218318 and 218448, 3/19/96, J. Garbus
PP#6F4762; DP#s 230634, 230635, 230636, and 230637; 4/25/97; L. Kutney
HED Metabolism Assessment Review Committee Decision Memo; DP# 251683, 12/30/98, W. Wassell

Adequate metabolism studies on grapes, peanuts, and wheat were submitted in conjunction with earlier azoxystrobin petitions, PP#s 5F4541 and 6F4762. Azoxystrobin undergoes photochemical isomerization to produce the *Z*-isomer and is extensively metabolized in plants. The parent compound undergoes cleavage of the ether linkages between the phenylacrylate and pyrimidinyl rings and the cyanophenyl and pyrimidinyl rings, with subsequent oxidation, hydrolysis, and/or reduction of the primary metabolites to form numerous secondary metabolites. Azoxystrobin is systemic. HED has determined that the residues of concern in/on plants for tolerance expression and risk assessment purposes are azoxystrobin and its *Z*-isomer.

860.1300 Nature of the Residue - Livestock

PP#5F4541; DP#s 218318 and 218448, 3/19/96, J. Garbus
PP#6F4762; DP#s 230634, 230635, 230636, and 230637; 4/25/97; L. Kutney
HED Metabolism Assessment Review Committee Decision Memo; DP# 251683, 12/30/98, W. Wassell

The nature of the residue in livestock is adequately understood based on acceptable metabolism studies conducted on goats and laying hens. HED has determined that the residue of concern in livestock is parent azoxystrobin only.

860.1340 Residue Analytical Methods

Enforcement methods

PP#s 5F4541 & 6F4762; DP# 235342, 5/30/97, C. Stafford
PP#7F4864; DP#s 249657 and 249668, 1/25/99, D. Dotson
PP#s 6F7106 & 7F7198; DP#s 334571 & 340016, 3/12/08, W. Cutchin

Crop commodities: A GC/NPD method, RAM 243/04, is available for the enforcement of tolerances for residues of azoxystrobin and its *Z*-isomer in crop commodities. The method has undergone method validation by Analytical Chemistry Branch/Biological and Economic Analysis Division (ACB/BEAD). The method was revised to incorporate comments made by BEAD, and the revised method (designated RAM 243, dated 5/15/98) has been submitted to FDA for inclusion in Pesticide Analytical Manual *(PAM)*, Volume II. The limit of quantitation (LOQ) is 0.01 ppm for each analyte in crop commodities.

Livestock commodities: A GC/NPD method, RAM 255/01, is available for the enforcement of tolerances for residues of azoxystrobin in livestock commodities. The method has been validated by ACB/BEAD for the analysis of milk and liver. The method LOQ is 0.0025 ppm and 0.01 ppm for each analyte in milk and tissues, respectively.

Data-collection method

Samples from the potato postharvest trial submitted with the current petition were analyzed for residues of azoxystrobin and its *Z*-isomer using LC/MS/MS Method RAM 305/03. This method has been reviewed previously by HED, under PP#s 6F7106 and 7F7198.

Briefly, samples were extracted with acetonitrile (ACN):water (90:10, v:v). After centrifugation, an aliquot of the extract was cleaned up on a C18 solid phase extraction column and analyzed using LC-MS/MS detection. The LC/MS/MS method uses a single ion transition, m/z 404.1→372.1, to quantitate azoxystrobin and R230310 residues in/on plant commodities. For confirmation, the LC/MS/MS method may be used to monitor additional ion transitions, m/z 404.1→344.0 and 404.1→329.0.

For potato postharvest samples, the LOQ, determined as the lower limit of method validation (LLMV), was 0.01 ppm for each analyte; the limit of detection (LOD) was not reported.

The method was verified prior to and in conjunction with sample analyses and is considered adequate based on acceptable method validation and concurrent recovery data. Samples of potato were fortified with azoxystrobin and its *Z*-isomer each at 0.01-10 ppm. The fortification levels used in method validation and concurrent method recovery were adequate to bracket expected residue levels.

Conclusions: There are adequate residue analytical methods for tolerance enforcement in crop and livestock commodities. The LC/MS/MS method used for determination of azoxystrobin and its *Z*-isomer in potato, RAM 305/03, was adequate for data collection purposes based on acceptable concurrent method recoveries.

860.1360 Multiresidue Methods

PP#5F4541; DP#s 218318 and 218448, 3/19/96, J. Garbus

Data have previously been submitted pertaining to the multiresidue methods testing of azoxystrobin in conjunction with the grape petition (PP#5F4541). The data indicate that azoxystrobin could not be recovered through application of the multiresidue protocols. These data have been forwarded to FDA for inclusion in *PAM* I.

860.1380 Storage Stability

PP#7F4864; DP#s 248887 and 249671, 10/14/98, D. Dotson, *et al.*
PP#7F4864; DP#s 249657 and 249668, 1/25/99, D. Dotson

Adequate storage stability data are available indicating that azoxystrobin and its *Z*-isomer are reasonably stable under frozen conditions in/on fortified samples of diverse crops. In previous studies, residues were determined to be stable for two years in/on apple, banana, carrot, cucumber, grape, leaf lettuce, rape seed, peach, winter wheat straw, wheat forage, and wine.

Over the two-year period, residues of both azoxystrobin and its *Z*-isomer decreased by up to 20% in winter wheat grain and by up to 27% (azoxystrobin only) in tomato, peanut, and pecan, but all recoveries were >70%; residues in these crops were stable (without decrease) for up to 6-8 months of storage.

Previous studies conducted on processed commodities demonstrated that fortified residues of azoxystrobin and its *Z*-isomer were generally stable under frozen conditions in peanut oil and meal, tomato juice and paste, and wheat bran for up to one year, and in soybean meal, corn grits, and orange oil, juice and pulp for at least two years.

Samples of postharvest potatoes from the submitted field trial study were stored frozen from harvest to analysis for up to 258 days (8.5 months). The available storage stability data on carrots may be translated to postharvest potatoes.

Table 4. Summary of Storage Conditions and Durations of Samples from Crop Field Trial Study.

Matrix	Analyte	Storage Temperature (°C)	Actual Storage Duration[1]	Limit of Demonstrated Storage Stability
Potato	Azoxystrobin	<-10	10-258 days (0.3-8.5 months)	Adequate storage stability data are available indicating that residues of azoxystrobin and R230310 are stable at <-15 °C for at least two years in/on soybean meal, corn grits, carrot root, leaf lettuce, grain sorghum forage, orange oil, and orange juice.[2] Additionally, data on file indicate residues of azoxystrobin and R230310 are stable for up to 2 years in cucumbers, apples, grapes, peaches, peanuts, pecans, rapeseed, tomatoes, bananas, and wheat grain.[3]
	R230310			

[1] Interval from sampling to analysis. Extracts were stored 0-3 days prior to analysis.
[2] Refer to DER for MRID 45738101 (DP# 287062; PMRA # 956496).
[3] Refer to DER for MRID 44452303; PMRA # 1191031.

Conclusions: There are adequate storage stability data from previous submissions to validate the storage conditions and durations of samples from the submitted postharvest potatoes. Residues of azoxystrobin and its *Z*-isomer were found to be relatively stable over a wide range of commodities under frozen storage conditions for up to 2 years. The potato residue data will not need to be corrected for loss of residue during frozen storage.

860.1400 Water, Fish, and Irrigated Crops

There are no proposed uses relevant to this guideline topic.

860.1460 Food Handling

There are no proposed uses relevant to this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

PP#6F4762; DP#s 230634, 230635, 230636, and 230637; 4/25/97; L. Kutney
PP#7F4864; DP#s 249657 and 249668, 1/25/99, D. Dotson

Tolerances for residues of azoxystrobin are currently established [40 CFR §180.507(a)(2)] for the fat (0.03 ppm), meat (0.01 ppm), and meat byproducts (0.07 ppm) of cattle, goat, horse, and sheep. A tolerance of 0.01 ppm each has been established for hog fat, meat, and meat byproducts. A milk tolerance of 0.006 ppm is also established. No tolerances for eggs and poultry meat and meat byproducts have been established.

Previously, the maximum theoretical dietary burdens (MTDBs) of azoxystrobin were estimated to be 51.3 ppm for beef, 40.4 for dairy cattle, 14.4 ppm for poultry, and 15.0 ppm for swine (DP# 362963 & 363046, M. Negussie, 08/20/09). The livestock feedstuffs associated with this petition are potato culls and processed potato waste; in addition, there are established tolerances for numerous livestock feedstuffs. Using Table 1 Feedstuffs (June 2008) and constructing reasonably balanced livestock diets, the previously estimated livestock dietary burdens of azoxystrobin were revised to include the processed potato waste (dairy cattle only) and are presented in Table 5. The dietary burdens of azoxystrobin are estimated at 51.3 ppm (beef), 44.4 ppm (dairy cattle), 14.4 ppm (poultry), and 15 ppm (swine).

Table 5. Calculation of Dietary Burdens of Azoxystrobin Residues to Livestock.

Feedstuff	Type[1]	% Dry Matter[2]	% Diet[2]	Recommended/ Established Tolerance (ppm)	Dietary Contribution (ppm)[3]
Beef Cattle					
Alfalfa hay	R	89	15	120	20.2
Aspirated grain fractions	CC	85	5	420	24.7
Barley grain	CC	88	35	3.0	1.19
Sorghum grain	CC	86	40	11	5.12
Canola meal	PC	88	5	1.0	0.057
TOTAL BURDEN	--	--	100	--	**51.3**
Dairy Cattle					
Alfalfa hay	R	89	20	120	27.0
Corn, field, silage	R	40	25	12	7.5
Sorghum grain	CC	86	35	11	4.5
Processed potato waste	CC	15	10	8	5.3
Canola meal	PC	88	10	1.0	0.114
TOTAL BURDEN	--	--	100	--	**44.4**
Poultry					
Sorghum grain	CC	86	75	11	8.25
Alfalfa meal	PC	89	5	120	6.0
Cottonseed meal	PC	88	20	0.6	0.12
TOTAL BURDEN	--	--	100	--	**14.4**
Swine					
Barley grain	CC	88	5	3.0	0.15
Sorghum grain	CC	86	80	11	8.8

Table 5. Calculation of Dietary Burdens of Azoxystrobin Residues to Livestock.					
Feedstuff	Type[1]	% Dry Matter[2]	% Diet[2]	Recommended/ Established Tolerance (ppm)	Dietary Contribution (ppm)[3]
Alfalfa meal	PC	89	5	120	6.0
Soybean meal	PC	92	10	0.5	0.05
TOTAL BURDEN	--	--	100	--	**15.0**

[1] R: Roughage; CC: Carbohydrate concentrate; PC: Protein concentrate.
[2] OPPTS 860.1000 Table 1 Feedstuffs (June 2008).
[3] Contribution = ([tolerance /% DM] X % diet) for beef and dairy cattle; contribution = ([tolerance] X % diet) for poultry and swine.

Comments
1) Alfalfa hay is chosen because it is the most widely used hay for cattle across the US.
2) Normally alfalfa hay will be given over alfalfa forage mainly because many production animals are in confined spaces and not grazing in pastures.
3) Canola and cottonseed meals are listed in diets, but could be replaced with soybean meal and not affect the proposed diets and total dietary burdens.
4) Rice grain could replace the barley grain for swine, but would not affect the total estimated dietary burden.

Adequate livestock feeding studies have been submitted previously for azoxystrobin. A dairy cattle feeding study was reviewed in conjunction with PP#6F4762 and a study with laying hens was reviewed in conjunction with PP#7F4864. In the cattle feeding study, cattle were dosed at levels of 5, 25, 75, and 250 ppm for 28-30 consecutive days. The dosing levels represent ~0.1x, 0.5x, 1.5x, and 4.9x the dietary burden for beef cattle, ~0.1x, 0.6x, 1.7x, and 5.6x the dietary burden for dairy cattle, and ~0.3x, 1.7x, 5x, and 16.7x the dietary burden for swine. Milk and tissue samples were analyzed for residues of azoxystrobin using the enforcement method for livestock commodities, with LOQs of 0.001 ppm for milk and 0.01 ppm for tissues and cream. The results of the cattle feeding study are summarized in Table 6.

In the poultry study, hens were dosed at levels of 60 ppm for 28 consecutive days; the dosing level represents 4.2x the dietary burden to poultry (the study included lower dose rates of 6.0 and 18 ppm; however, these samples were not analyzed). Egg and tissue samples were analyzed for residues of azoxystrobin using the enforcement method for livestock commodities, with an LOQ of 0.01 ppm for each matrix. No quantifiable residues were found in any poultry commodity (see Table 6).

Table 6. Summary of Azoxystrobin Residues in Livestock Matrices Following the Oral Administration of Azoxystrobin over 28-30 Consecutive Days.					
Dose Rate in Diet (mg/kg)	Azoxystrobin Residues (ppm)				
	Milk/Eggs	Muscle	Fat	Kidney	Liver
Dairy Cattle					
5	<0.001-0.003	<0.01	<0.01	<0.01	<0.01
25	<0.001-0.006	<0.01	<0.01	<0.01	<0.01-0.01
75	<0.001-0.004	<0.01	<0.01-0.03	<0.01-0.01	0.01-0.05
250	0.002-0.009	<0.01	0.01-0.03	0.01-0.02	0.03-0.07
Laying Hens					
60	<0.01	<0.01	<0.01	Not analyzed	<0.01

Conclusions: The existing azoxystrobin tolerances for milk and the fat, meat, and meat byproducts of cattle, goat, hog, horse, and sheep are adequate; no revision to the existing tolerances is needed to support the proposed uses of azoxystrobin.

The proposed uses of azoxystrobin addressed in this document do not alter the Agency's previous conclusion that there is no reasonable expectation of finite residues in poultry commodities [Category 3 of §180.6(a)]. No tolerances are needed for poultry tissues or eggs.

860.1500 Crop Field Trials

Other than the postharvest potato field trial data (MRID 48437101), no new residue field trial data were submitted to support the proposed tolerances. The changes are a result of revised crop groups and are conversions from existing groups/subgroups or representative commodities. The proposed tolerances for the dragon fruit and wasabi are extrapolated from existing azoxystrobin tolerances on mango (2.0 ppm) and herb subgroup 19A, fresh (50 ppm), respectively.

Tuberous and corm vegetables subgroup 1C (Potato-Post Harvest)

DER Reference: 48437101.der1.doc

Syngenta submitted residue data for azoxystrobin on potatoes following postharvest treatment. Five postharvest trials were conducted in the United States and Canada in 2009-2010 in the North American Free Trade Agreement (NAFTA) Growing Zones 1 (ME; 1 trial), 5A (WI; 1 trial), 5 (ON; 1 trial), and 11 (WA and ID; 2 trials).

Potatoes were grown on-site by the trial personnel in the US trials and were obtained from a commercial grower in the Canadian trial. Samples of mature potato tubers were harvested from all trials, placed in on-site storage for ~1-4 months, and then treated with a spray mixture containing a 3.00 lb ai/gal (360 g a.i./L) difenoconazole flowable suspension (FS) formulation, a 2.09 lb ai/gal (250 g a.i./L) azoxystrobin soluble concentrate (SC) formulation, and a 1.92 lb ai/gal (230 g a.i./L) fludioxonil SC formulation.

In all trials, the test mixture was applied as a postharvest treatment spray directed to tubers falling from a conveyor belt or moving along a roller table (TRT 02). At the ID trial, three additional treatment scenarios were included: surface spray directed to tubers on a tarp (TRT 03); spray directed to tubers in a spray chamber (TRT 04); and spray directed to tubers on a brush table (TRT 05). For each treatment, azoxystrobin was applied at a rate of 0.0089-0.0099 lb ai/2000 lb potatoes (4.0309-4.5105 g ai/2000 lb potatoes, (0.44-0.50 g a.i./100 kg potatoes) using water as the carrier; the delivery rate was 0.22-0.54 gal/2000 lb potatoes (0.09-0.23 L/100 kg potatoes).

Samples of potatoes from each trial site were collected after the test substance had dried on the day of application [0 days after application (DAA)]. At three sites (WA, ON, and ID), additional treated samples were collected and placed in storage for 13-14, 30-32, 59-61, and/or 231 days after application to generate residue decline data.

Potato samples were analyzed for residues of azoxystrobin and its metabolite R230310 using LC/MS/MS; modified Syngenta Analytical Method RAM 305/03 (MRID# 47096401; PMRA #

2044022). This method has been reviewed previously and deemed acceptable for data gathering. The limit of quantitation (LOQ; determined as the lowest limit of method validation, LLMV) was 0.01 ppm for both analytes. The method was verified prior to and in conjunction with sample analyses and is considered adequate based on acceptable method validation and concurrent recovery data. The fortification levels used in method validation and concurrent method recovery were adequate to bracket expected residue levels.

Potato samples were stored at <-10 °C prior to analysis for a maximum of 258 days (8.5 months). All samples were analyzed within 0 to 3 days of extraction. Adequate storage stability data are available indicating that residues of azoxystrobin and R230310 are stable at <-15 °C for at least 24 months in/on soybean meal, corn grits, carrot root, leaf lettuce, grain sorghum forage, orange oil, and orange juice (MRID 45738101; PMRA # 956496). Additionally, data on file indicate residues of azoxystrobin and R230310 are stable for up to 2 years in cucumbers, apples, grapes, peaches, peanuts, pecans, rapeseed, tomatoes, bananas, and wheat grain (MRID 44452303; PMRA # 1191031). These data may be translated to potatoes to validate the storage durations and conditions of azoxystrobin and R230310 for the potato field trial samples (OECD Guidelines for the Testing of Chemicals, Test No. 506, Adopted 16 October, 2007).

Residues of azoxystrobin were 0.992-4.15 ppm (per trial average residues were 0.994-3.79 ppm) in/on potatoes collected 0 DAA following one postharvest spray treatment application of azoxystrobin formulated as a 2.09 lb ai/gal (250 g a.i./L) SC at a total seasonal rate of 0.0089-0.0099 lb ai/2000 lb potatoes (0.44-0.50 g a.i./100 kg potatoes). Residues of R230310 were all <LOQ (0.01 ppm). All application methods (directed spray to tubers on a conveyor belt, roller table, stationary surface, spray chamber, or brush table) resulted in similar residue levels.

In the ON decline trial, residues of azoxystrobin remained constant; residues of azoxystrobin from the WA and ID trials generally decreased with increasing DAA. Residues of R230310 were <LOQ at each sampling interval; therefore, residue decline could not be assessed for the metabolite.

Table 7. Summary of Residue Data from Potato Crop Field Trials with Azoxystrobin.

Commodity	Analyte	Total App. Rate		DAA	Residue Levels (ppm)[1]							
		g a.i./ 2000 lb	lb a.i./ 2000 lb [g a.i./100 kg		n	Sample Min.	Sample Max.	LAFT[3]	HAFT[3]	Median	Mean	Std. Dev.[4]
TRT 02 (Conveyor Belt or Roller Table)												
Potato tubers	Azoxystrobin	4.0473-4.5105	0.0089-0.0099 [0.45-0.50]	0	10	0.992	4.15	0.994	3.79	2.22	2.40	1.20
	R230310				10	<0.01	<0.01	0.01	0.01	0.01	0.01	N/A
	Total Residues				10	<1.002	<4.16	1.004	3.80	2.23	2.41	1.20
TRT 03 (Surface)/Stationary												
Potato tubers	Azoxystrobin	4.0997	0.0090 [0.45]	0	2	1.05	1.22	1.14	1.14	N/A	N/A	N/A
	R230310				2	<0.01	<0.01	0.01	0.01	N/A	N/A	N/A
	Total Residues				2	<1.06	<1.23	1.15	1.15	N/A	N/A	N/A
TRT 04 (Spray Chamber)												
Potato tubers	Azoxystrobin	4.0309	0.0089 [0.44]	0	2	3.50	3.57	3.54	3.54	N/A	N/A	N/A
	R230310				2	<0.01	<0.01	0.01	0.01	N/A	N/A	N/A

Table 7. Summary of Residue Data from Potato Crop Field Trials with Azoxystrobin.

Commodity	Analyte	Total App. Rate		DAA	Residue Levels (ppm)[1]							
		g a.i./ 2000 lb	lb a.i./ 2000 lb [g a.i./100 kg		n	Sample Min.	Sample Max.	LAFT[3]	HAFT[3]	Median	Mean	Std. Dev.[4]
	Total Residues				2	<3.51	<3.58	3.55	3.55	N/A	N/A	N/A
TRT 05 (Brush Table)												
Potato tubers	Azoxystrobin	4.0850	0.0090 [0.45]	0	2	2.23	2.31	2.27	2.27	N/A	N/A	N/A
	R230310				2	<0.01	<0.01	0.01	0.01	N/A	N/A	N/A
	Total Residues				2	<2.24	<2.32	2.28	2.28	N/A	N/A	N/A
Combined Treatments												
Potato tubers	Azoxystrobin	4.0309-4.5105	0.0089-0.0099 [0.44-0.50]	0	16[1]	0.992	4.15	--	--	2.25	2.37	1.12
					8[2]	--	--	0.994	3.79	2.25	2.37	1.15
	R230310				16[1]	<0.01	<0.01	--	--	0.01	0.01	N/A
					8[2]	--	--	0.01	0.01	0.01	0.01	N/A
	Total Residues				16[1]	<1.002	<4.16	--	--	2.26	2.38	1.12
					8[2]	--	--	1.004	3.80	2.25	2.37	1.15

[1] n = no. of samples. For calculation of median, mean, and standard deviation, the LOQ (0.01 ppm) was used for any results reported as <LOQ in Table C.3.
[2] n = no. of field trials; statistical calculations are based on per-trial average values.
[3] LAFT = lowest-average-field-trial; HAFT = highest-average-field-trial.
[4] N/A = Not applicable.

Conclusions: The supervised residue trials on potato are considered scientifically acceptable. Based on the study results, residues of azoxystrobin may be up to 4.15 ppm (per trial average maximum of 3.79 ppm) in/on potato collected at 0 DAA following postharvest spray application of azoxystrobin, formulated as a 2.09 lb ai/gal SC, at a total rate of 0.0089-0.0099 lb ai/2000 lb potatoes (4.0309-4.5105 g a.i./2000 lb potatoes); maximum residues of metabolite R230310 in potatoes were <0.01 ppm. Samples were analyzed for azoxystrobin and the metabolite R230310 using acceptable methods. The study is supported by adequate storage stability data for azoxystrobin and R230310.

The average residue values for the potato postharvest use were used to calculate the tolerance. Using the OECD statistical procedures, the recommended tolerance is 8 ppm. The recommended tolerance is higher than the proposed tolerance (6 ppm). Thus, a revised Section F is required to reflect this determination.

Note to PM: The existing separate tolerance on potato should be removed and the established vegetable, tuberous and corm, subgroup 1C need to be revised.

<u>Crop Field Trial Data in Support of Crop Group/Subgroup Expansions.</u>

The adequacy of the available data to support the crop group/subgroup expansions is discussed below for each crop and/or crop group/subgroup.

Caneberry subgroup 13-07A
Residue Chemistry Memo DP# 279210, N. Dodd, 06/19/02
DER Reference: 45522301

Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on caneberry subgroup 13A at 5.0 ppm. Tolerances were established based on the results from three crop field trials conducted in OR (2 trials) and WA (1 trial) in/on raspberry or blackberry and cranberry. Azoxystrobin (80% WDG) was applied to raspberry or blackberry plants as 6 or 7 foliar directed spray applications at 0.24-0.26 lb ai/A/application, for a total of 1.5-1.8 lb ai/A/season (1-1.2x the maximum proposed rate). Caneberry fruits were harvested on the day of the last application (0-day PHI). The combined residues of azoxystrobin and R230310 were <0.69-3.69 ppm in/on samples of caneberry (4 raspberry and 2 blackberry) fruit.
The required number of field trials for blackberry or raspberry as representative crops to establish a tolerance for the caneberry subgroup 13-07A is 3 trials for any one blackberry or raspberry (ChemSAC 7/8/2009).

Bushberry subgroup 13-07B
Residue Chemistry Memo DP# 274312, G. J. Herndon, 07/10/2001
DER Reference: 45253901

Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on bushberry subgroup 13B at 3.0 ppm. The tolerances were established based on the results from the supervised crop field trials in blueberries. Seven trials conducted in Regions 1 (ME; 1 trial), 2 (NC; 2 trials), 5 (MI; 3 trials), and 12 (OR; 1 trial) were submitted. The results have shown that the maximum residues in blueberry treated six times with Quadris 80WG at 0.25 lbs ai/A/application (equivalent to 1X the proposed rate) and collected 0 days following the last application were 1.63 ppm.

The required number of field trials for highbush blueberry as the representative crop to establish a tolerance for the bushberry subgroup 13-07B is 8 trials for highbush blueberry (ChemSAC 7/8/2009).

Small fruit vine climbing, except fuzzy kiwifruit subgroup 13-07F
Residue Chemistry Memo DP# 218318 & 218448, DP#226232, J. Garbus, 3/19/96
DER References: 43678209, 43678210 and 44002200

Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on grapes at 1.0 ppm based on trials conducted in Europe and the US. Seven of the trials were conducted in the US at 6 sites; Regions 1 (NY; 1trial); 11 (WA; 1 trial); 10 (CA; 3 trials) and 1 trial each in AK and MI, areas not generally associated with viticulture. In addition, nine field trials were conducted in the US in Region 1 (NY; 1 trial), Region 10 (CA; 6 trials), and Region 11 (OR and WA; 2 trials) to satisfy the requirement for geographic representation. The results of 10 other trials conducted in Europe are also available. The results from the US trials have shown that the maximum residues in grapes, harvested 12 to 19 days following the last application of a wettable granular (WG) formulation, and treated six times at 0.25 lbs ai/A/application, equivalent for a total of 1.5 lbs ai/A/season (1X the proposed rate), were 0.81 ppm.

The required number of field trials for grapes as the representative crop to establish a tolerance for the fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F is 12 trials for grapes (ChemSAC 7/8/2009).

Note to PM: The existing separate tolerance on grape should be removed when the subgroup tolerance is established.

Berry, low growing, subgroup 13-07G, except cranberry.
Residue Chemistry Memo DP# 274312, G. J. Herndon, 07/10/2001
DER Reference: 45205604

Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on strawberry at 10.0 ppm. The tolerances were established based on the results from the supervised crop field trials on strawberries. Seven trials conducted in Regions 3 (FL; 2 trials), 5 (WI; 1 trial), 10 (CA; 3 trials), and 12 (OR; 1 trial) were submitted. The results from the crop field trials on strawberry have shown that the maximum residues in strawberry treated six times with Quadris 80WG at 0.25 lbs ai/A/application (equivalent to 1X the proposed rate) and collected 0 days following the last application were 5.11 ppm.

The required number of field trials for strawberry as the representative crop for the berry, low growing, subgroup 13-07G, except cranberry is 8 trials for strawberry (ChemSAC 7/8/2009).

Note to PM: The existing separate tolerance on strawberry should be removed when the subgroup tolerance is established.

Citrus Fruits
Residue Chemistry Memo DP# 260134, M. J. Nelson, 09/06/2000
Residue Chemistry Memo DP# 312949, W. Cutchin, 01/23/2006
DER References: 44915217, 44915224, and 44915225
DER Reference: 46509101CFT

Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on fruit, citrus, group 10 at 10 ppm. Twenty-three field trials were conducted on the representative crops (sweet orange, lemon, and grapefruit). Six trials were conducted on grapefruit in Regions 3 (FL; 3 trials), 6 (TX; 1 trial), and 10 (CA; 2 trials); 5 trials were conducted on lemons in Regions 3 (FL; 1 trial) and 10 (CA, AZ; 4 trials); and 12 trials were conducted on oranges in Regions 3 (FL; 8 trials), 6 (TX; 1 trial), and 10 (CA; 3 trials). Residues of azoxystrobin were 0.16-0.41 ppm in/on grapefruit, 0.27-0.74 ppm in/on lemons, and 0.09-0.53 Fppm in/on oranges harvested 0 days following the last of six applications, with 6- to 8-day retreatment intervals, of the 80% WDG formulation at 0.25 lb ai/A/application, for a total application rate of 1.5 lb ai/A/season (1x the maximum proposed seasonal application rate).

In addition, citrus field trials treated with both preharvest and postharvest applications were submitted. The submitted data were obtained from trials conducted in Regions 3 (FL; 1 trial), 6 (TX; 1 trial), and 10 (CA; 4 trials). For pre-harvest, treated plot received two foliar applications at ~ 0.25 lb a.i./A/A and harvested at 0-day PHI.

All post-harvest test solutions contained Azoxystrobin 80WG and were applied at 1.0 lb a.i./100 gal water (dip) and 1.0 lb a.i./250,000 lb fruits (packing-line spray). Citrus field trials were conducted using simulated postharvest applications (using six different postharvest methods) following normal pre-harvest use. The highest azoxystrobin residues were detected in grapefruit, orange, and lemon samples that received pre-harvest as well as postharvest dip treatments ranging from 1.185 to 5.427 ppm, 1.213 to 3.994 ppm, and 1.466 to 9.182 ppm, respectively. Based on these field trial data, the tolerance was established on the citrus fruit group 10 at 10.0 ppm.

Onion, bulb, subgroup 3-07A and Onion, green, subgroup 3-07B
Residue Chemistry Memo DP# 260134, M. J. Nelson, 09/06/2000
DER References: 44915210 and 44915226

Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on onion, bulb and onion, green at 1.0 and 7.5 ppm, respectively. The tolerances were established based on the results from crop field trials on bulb onions and green onions. Eight bulb onion field trials were conducted in Regions 1 (NY; 1 trial), 5 (IL; 1 trial), 6 (TX; 1 trial), 8 (CO; 1 trial), 10 (CA; 2 trials), 11 (WA; 1 trial), and 12 (OR; 1 trial). Three green onion trials were conducted in Regions 6 (TX; 1 trial) and 10 (CA and AZ; 1 trial each).

The results have shown that the maximum residues in bulb onions and green onions treated six times with Quadris 80 WDG at 0.25 lbs ai/A/application (equivalent to 1X the proposed rate of 1.5 lb ai/A/season) and collected 0 days following the last application were 0.67 and 6.91 ppm, respectively.

Rapeseed subgroup 20A
Residue Chemistry Memo DP# 312949, W. Cutchin, 01/23/2006
DER Reference: 46046604CFT
Residue Chemistry Memo PP#s 7F4864 & 8F4995, DP Barcode: D249657 & D249668, D. Dotson, 1/25/99
DER References: 44613502 and 44595108

Canola is the representative crop for the rapeseed subgroup 20A. Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on canola, seed at 1.0 ppm and rapeseed, seed at 0.5 ppm. Eleven crop field trials s for azoxystrobin in/on canola were submitted. Nine of these trials were conducted in Canada and two were conducted in the U.S., in Regions 7 (ND) and 11 (WA). Azoxystrobin was applied (WDG 80%) as a foliar broadcast spray at the target rate of 0.15 lb ai/A-0.34 lb ai/A/application. The label specifies a use rate of 0.1-0.25 lb ai/acre/application with a maximum of three applications and a maximum rate of 0.45 lb ai/acre/season. The highest application rate was three applications of 0.17, 0.34, and 0.34 lb ai/acre which result in a total application of 0.85 lb ai/acre/season. This rate is 1.9x the maximum rate specified on the label (0.45 lb ai/acre/season). The highest field trial value for the combined residues of azoxystrobin and R230310 was 0.80, which was obtained from application of azoxystrobin at a rate of 1.9x the maximum rate specified on the label.

In addition, there is existing field trial data from nine trials conducted in Canada encompassing Regions V (MB), VII (SK), and XIV (AB [3], SK [2], MB [2]) in or on canola treated with Quadris 2.08 SC. This formulation was applied three times as a foliar broadcast spray at the target rate of ~0.11 lb ai/A (0.123 kg ai/ha) for the first and third applications and at the target rate of ~0.23 lb ai/A (0.258 kg ai/ha) for the second application. The target seasonal application rate for the treated plots was 0.45 lb ai/A (0.504 kg ai/ha). The maximum residues found for azoxystrobin and R230310 were 0.23 ppm and 0.02 ppm, respectively. Based on these data, tolerances were established at 0.5 ppm in Indian rapeseed, Indian mustard seed, field mustard seed, black mustard seed, flax seed, sunflower seed, safflower seed, and crambe seed.

Tolerances on canola seed were established at 1.0 ppm using the highest use rate tested. The 1.0 ppm tolerance level is adequate to cover the rapeseed subgroup 20A.

Note to PM: The existing separate tolerances on canola, seed; crambe, seed; flax, seed; rapeseed, seed; rapeseed, Indian; mustard, field seed; and mustard, Indian, seed should be removed when the subgroup tolerance is established.

Sunflower subgroup 20B

Residue Chemistry Memo DP# 312949, W. Cutchin, 01/23/2006
DER References: 46046601CFT and 46046602

Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on sunflower seeds at 0.5 ppm. The tolerances were established based on submitted data from six trials in the USA encompassing Regions 5 (MN and ND; 2 trials), 7 (NE, ND, and SD; 3 trials), 8 (TX; 1 trial), and four trials in Canada encompassing Regions 5 (MB; 1 trial), 7 (SK; 1 trial), 14 (AB and MB; 2 trials). In the USA, azoxystrobin was applied as Quadris 80 WG, containing 81.4% azoxystrobin. In Canada, azoxystrobin was applied as Quadris 2.08 SC, which is a soluble concentrate containing 22.8% azoxystrobin. Both formulations were applied three times as a foliar broadcast spray at the target rate of ~0.11 lb ai/A/application for the first and third applications and at the target rate of ~0.23 lb ai/A/application for the second application. The target seasonal application rate for the treated plots was ~0.45 lb ai/A. The results from these trials have shown that the maximum residues in sunflower seeds collected 28-30 days following the last application are 0.24 ppm and 0.01 ppm for azoxystrobin and R230310, respectively.

Note to PM: The existing separate tolerances on sunflower, seed and safflower, seed should be removed when the subgroup tolerance is established.

Cottonseed subgroup 20C

Cotton
Residue Chemistry Memo DP# 334571, W. Cutchin, 03/12/2008
DER Reference: 47096402

Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on cotton, undelinted seed at 0.6 ppm and in/on cotton, gin byproducts at 45 ppm. Twelve cotton field trials were conducted in the United States in Regions 2 (SC; 1 trial), 4 (AR, LA, MS; 3 trials), 6 (TX; 1 trial), 8 (NM, OK, TX; 4 trials), and 10 (CA; 3 trials). The treated plot received one in-furrow application of a 2.08 lb/gal FlC formulation of azoxystrobin at planting of cotton at a target rate 0.15 lb ai/A/application, followed by three foliar broadcast applications of the 2.08 lb/gal FlC formulation at a rate of 0.14-0.16 lb ai/A/application. The in-furrow rate and foliar treatment rates are equivalent to 1-1.9x the proposed maximum seasonal rate. Cottonseed was harvested 45 days after last application (DALA), and samples from 6 trials (3 picker harvested; 3 stripper harvested) were ginned for cotton gin byproducts (trash). The results from the crop field trials on cotton have shown that maximum combined residues (azoxystrobin + R230310) were 0.62 ppm in/on cottonseed and 34.4 ppm in/on cotton gin byproducts.

Note to PM: The existing separate tolerance on undelinted, seed should be removed when the subgroup tolerance is established.

Tomato subgroup 8-10A
Residue Chemistry Memo DP# 328984; W. Cutchin; 06/19/2006
DER References: 44058730 and 44058731

Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on tomato at 0.2 ppm. A total of 16 field trials were conducted in Regions 1 (NJ; 1 trial), 2 (NC; 1 trial), 3 (FL; 2 trials), 5 (IN; 1 trial), and 10 (CA; 11 trials). The results from the crop field trial on tomatoes have shown that the maximum combined residues in/on tomatoes treated eight times with Quadris 80WDG at 0.1 lb ai/A/application (equivalent to 1X the proposed rate) and collected 1 day following the last application were 0.18 ppm.

Pepper/eggplant subgroup 8-10B
Residue Chemistry Memo DP# 274312, G. J. Herndon, 07/10/2001
Residue Chemistry Memo DP# 328984, W. Cutchin, 06/19/2006 (PP# 1E06264)
DER Reference: 45332502

Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on vegetable, fruiting, group 8, except tomato at 2.0 ppm. The tolerances were established based on the results from eight supervised field trials on peppers (bell and non-bell) conducted in Regions 1 (NY; 2 trials), 2 (GA; 1 trial), 3 (FL; 2 trials), 5 (OH; 1 trial), 6 (TX; 1 trial), and 10 (CA; 2 trials). Bell and non-bell pepper data (PP#1E6264) were used to establish the okra and eggplant tolerances as a result of a previous request from IR-4 (DP# 274312, G. Herndon, 4/30/01). The results from the crop field trial on peppers have shown that the maximum residues in bell peppers and non-bell peppers treated six times with Quadris 80WDG at 0.25 lbs ai/A/application (equivalent to 1X the proposed rate) and collected 0 days following the last application were 0.40 ppm and 0.92 ppm, respectively.

Note to PM: The existing separate tolerance on okra should be removed when the subgroup tolerance is established.

Dragon-fruit
Residue Chemistry Memo DP# 274312, G. J. Herndon, 07/10/2001
DER Reference: 45205606

Tolerances have been established for the combined residues of azoxystrobin and its *Z*-isomer in/on mango at 2 ppm. The tolerance was established based on the results from the supervised crop field trials on mango conducted in Region 13 (FL; 3 trials). The results from the crop field trials have shown that the maximum residues in mango treated six times with 80WG (containing 80% a.i.) at 0.25 lbs ai/A/application (equivalent to 1X the proposed rate) and collected 0 days following the last application were 0.48 ppm. The mango tolerance of 2.0 ppm can be translated to dragon-fruit; both are classified as tropical fruit with inedible peels (ChemSAC 2/9/2011).

Wasabi

Residue Chemistry Memo DP# 285603, N. Dodd, 01/22/2003
Residue Chemistry Memo DP# 312949, W. Cutchin, 01/23/2006
DER References: 45736301, 46006901, and 46219201

IR-4 is proposing to extrapolate the established tolerances of azoxystrobin on the herb subgroup 19A, fresh leaves at 50 ppm. In addition, IR-4 is requesting that application be allowed through chemigation for wasabi. The existing herb and spice tolerances were established using crop field trials (basil, chive and dill seed) conducted using foliar broadcast sprays at 0.25 lb ai/A/application with a maximum seasonal rate of 1.25 lb ai/A, with a pre-harvest interval of 0-days. The use pattern proposed for wasabi is similar to the current use directions for herbs and spices except for addition of application through chemigation. The tolerances on the herb subgroup 19A, fresh leaves are adequate to cover a tolerance of 50 ppm for wasabi, fresh and the herb subgroup 19A, dried leaves at 260 ppm to establish tolerances on wasabi, dry (ChemSAC, 2/23/2011). The petitioner is required to submit a revised Section F to propose a tolerance for residues of azoxystrobin in/on wasabi, dry at 260 ppm.

Conclusions. The existing azoxystrobin tolerances on onion, bulb; onion, green; tomato; grape; strawberry; juneberry; lingonberry; salal; cotton, undelinted seed; canola, seed; crambe, seed; flax, seed; rapeseed, seed; rapeseed, Indian; mustard, field seed; mustard, Indian, seed; sunflower, seed; safflower, seed; vegetable, fruiting, group 8, except tomato; fruit, citrus, group 10; caneberry subgroup 13-A; and bushberry subgroup 13-B are sufficient to support the proposed revisions to tolerances. Adequate geographic representation and residue data are available.

860.1520 Processed Food and Feed

DER Reference: 48437101.der2.doc

Syngenta submitted a processing study for azoxystrobin on potato following postharvest treatment. One postharvest trial was conducted in Kimberley, ID, in 2009. Potatoes were grown on-site and mature potato tubers were harvested, placed in on-site storage for ~2 months, and then treated with a spray mixture containing a 3.00 lb ai/gal (360 g a.i./L) difenoconazole flowable suspension (FS) formulation, a 2.09 lb ai/gal (250 g a.i./L) azoxystrobin soluble concentrate (SC) formulation, and a 1.92 lb ai/gal (230 g a.i./L) fludioxonil SC formulation. The test mixture was applied as a postharvest treatment spray directed to tubers falling from a conveyor belt at 1X the application rate of 0.0091 lb azoxystrobin/2000 lb potatoes (4.1357 g azoxystrobin/2000 lb potatoes [0.46 g a.i./100 kg potatoes]) using water as the carrier. The delivery rate was 0.51 gal/2000 lb potatoes (0.21 L/100 kg potatoes). Potato samples were collected after the spray had dried on the day of application [0 days after application (DAA)] and processed into flakes, chips, and wet peel by the University of Idaho Food Technology Center (Caldwell, ID) using simulated commercial procedures. Adequate descriptions were provided of the processing procedures, including material balance summaries.

Potato raw agricultural commodity (RAC) and processed fraction samples were analyzed for residues of azoxystrobin and its metabolite R230310 using modified Syngenta Method RAM 305/03 (MRID 47096401; PMRA # 2044022), an LC/MS/MS method. This method has been reviewed previously and deemed acceptable for data gathering. The limit of quantitation (LOQ;

determined as the lowest limit of method validation, LLMV) was 0.01 ppm for azoxystrobin and R230310 in all potato matrices. The method was verified prior to and in conjunction with sample analysis and is considered adequate based on acceptable method validation and concurrent recovery data. The fortification levels used in method validation and concurrent method recovery were adequate to bracket expected residue levels.

The maximum storage durations of samples from collection/processing to analysis were 140 days (4.6 months) for potato (RAC), 209 days (6.9 months) for flakes, 222 days (7.3 months) for chips, and 166 days (5.5 months) for wet peel. Analysis took place between 0 and 3 days after extraction. Adequate storage stability data are available indicating that residues of azoxystrobin and R230310 are stable at <-15 °C for at least 24 months in/on soybean meal, corn grits, carrot root, leaf lettuce, grain sorghum forage, orange oil, and orange juice (MRID 45738101; PMRA # 956496). Additionally, data on file indicate residues of azoxystrobin and R230310 are stable for up to 2 years in cucumbers, apples, grapes, peaches, peanuts, pecans, rapeseed, tomatoes, bananas, and wheat grain (MRID 44452303; PMRA # 1191031). According to the OECD Guidelines for the Testing of Chemicals (Test No. 506, Adopted 16 October, 2007), if there is no observed decline of residues across the range of five different commodity categories (high water content, high oil content, high protein content, high starch content, and high acid content), then residues are stable in all commodities, and specific freezer storage stability data for processed foods are not needed. Therefore, there are no concerns regarding the stability of azoxystrobin and R230310 residues in any samples in this study.

Concentration of residues in potatoes treated with one postharvest treatment of azoxystrobin (4.1357 g azoxystrobin/2000 lb potatoes [0.46 g a.i./100 kg potatoes]) following processing was not observed in potato processed fractions. Mean residues of azoxystrobin were 0.938 ppm for potato tuber (RAC), <0.01 ppm for flakes, 0.0111 ppm for chips (resulting in a processing factor of 0.01x), and 0.846 ppm for wet peel (resulting in a processing factor of 0.90x). Residues of metabolite R230310 were below the LOQ (<0.01 ppm) in/on all samples of potato RAC, flakes, chips, and wet peel. Therefore, no processing factors were calculated for R230310. All of the processing factors calculated in this study were less than the maximum theoretical concentration factors of 4.7x for dried potatoes (flakes and granules) and 4.0x for processed waste (based on loss of water and separation of components; OPPTS 860.1520, Tables 2 and 3; DIR98-02, Section 10).

Table 8. Residue Data from Potato Processing Studies with Azoxystrobin.

RAC	Processed Commodity	Total Rate		DAA	Residues (ppm)			Processing Factor[1,2]		
		g a.i./ 2000 lb	lb a.i./ 2000 lb		Azoxystrobin	R230310	Total Residues	Azoxystrobin	R230310	Total Residues
Potato	Tubers (RAC)	4.1357	0.0091	0	0.938	<0.01	<0.948	--	--	--
	Flakes				<0.01	<0.01	<0.02	<0.01x	NC	<0.02x
	Chips				0.0111	<0.01	<0.0211	0.01x	NC	<0.02x
	Wet peel				0.846	<0.01	<0.856	0.90x	NC	<0.90x

[1] NC = Not calculated; residues were below the LOQ (<0.01 ppm for all in analytes) in the RAC and processed fraction.
[2] Processing Factor = [Measured residue for analyte in the processed fraction] / [Measured residue for analyte in the RAC].

Conclusion: The submitted potato processing study is acceptable. Processing of the tuber RAC with quantifiable residues of azoxystrobin did not result in the concentration of residues in potato fractions (processing factors were all <1x). Residues of R230310 were below the LOQ in/on all samples of potato RAC, flakes, chips, and wet peel. Therefore, processing factors were not calculated. The observed concentration factors were less than the theoretical concentration factors.

Acceptable methods were used for the determination of residues of azoxystrobin and the *Z*-isomer metabolite. The sample storage conditions and durations for azoxystrobin analyses are supported by adequate storage stability data.

860.1650 Submittal of Analytical Reference Standards

Analytical standards for azoxystrobin and its *Z*-isomer are currently available in the EPA National Pesticide Standards Repository (personal communication with Charles Stafford, ACB, 07/07/2011) with an expiration date of 11/30/2014.

860.1850 Confined Accumulation in Rotational Crops

PP#6F4762; DP#s 230634, 230635, 230636, and 230637, L. Kutney, 4/25/97
PP#9F6058; DP# 260134, 9/6/00, M. Nelson

Adequate confined studies have previously been presented in PP#6F4762 and re-evaluated in PP#9F6058. Total radioactive residues, expressed as [^{14}C]azoxystrobin equivalents, accumulated at >0.01 ppm in the raw agricultural commodities of lettuce, radishes, and wheat planted in sandy loam soil 30, 200, and 365 days after treatment of the soil with [^{14}C]azoxystrobin at 1.8 lb ai/A. Residues were highest in rotated crop commodities from the 30-day PBI and declined in subsequent PBIs.

Azoxystrobin was identified in all rotated crop commodities at the 30-day PBI. In 30-day PBI samples, the *Z*-isomer was only identified in wheat forage and straw. Compound 42 was the major metabolite identified in 30-day PBI lettuce and wheat forage and straw. In 30-day PBI radish roots, azoxystrobin was the major metabolite and in 30-day PBI radish tops, metabolites G_2, N_1, and N_2 were the major metabolites. In 30-day PBI wheat grain, ^{14}C-starch was found to account for the largest portion of radioactivity. Several conjugated metabolites (compound 42 and the M, N, and O metabolites) of primary crop metabolites were identified, indicating that azoxystrobin is more extensively metabolized in rotational crops than in primary crops. HED has concluded that the residues of concern in rotational crops are parent and the *Z*-isomer.

860.1900 Field Accumulation in Rotational Crops

PP#6F4762; DP#s 230634, 230635, 230636, and 230637, 4/25/97, L. Kutney
PP#9F6058; DP#s 283588 and 287062, N. Dodd, 2/6/03
PP#9F6058; DP# 298114, L. Cheng, 12/20/05
PP#s 6F7106 & 7F7198; DP# 334571 & 340016, W. Cutchin, 3/12/08

Limited field rotational crop studies, reflecting applications made to the primary crop at a seasonal rate of 0.8 lb ai/A, were initially submitted in PP#6F4762. Subsequently, additional limited field rotational crop studies, with applications made to the primary crop at seasonal rates of 1.6 or 2.0 lb ai/A, were submitted and reviewed in PP#9F6058. Under PP#s 6F7106 and 7F7198, HED concluded that the following PBIs were appropriate to support a maximum seasonal application rate of 2.0 lb ai/A to rotated crops: 12 months for buckwheat, millet, oats and rye; and 36 days for the leafy vegetables (except *Brassica*) crop group; the *Brassica* leafy greens subgroup; the root vegetables subgroup; the tuberous and corm vegetable subgroup; and the leaves of root and tuber vegetables group. Crops with registered uses may be planted immediately after the last treatment unless otherwise specified. For crops not on the label, a 12-month PBI must be observed unless otherwise specified.

Conclusions: Because the proposed amended uses do not result in increased maximum seasonal application rates of azoxystrobin, no changes to the existing rotational crop restrictions are needed. The rotational crop restrictions on the label for EPA Reg. No. 100-1098 is adequate.

860.1550 Proposed Tolerances

HED has determined that the residues of concern in/on crop commodities for tolerance expression and risk assessment purposes are azoxystrobin and its *Z*-isomer. The tolerance expression proposed by IR-4 for the proposed/revised tolerances is adequate.

Adequate field trial data have been submitted for the postharvest use of tuberous and corm vegetables subgroup 1C. The OECD statistical calculation procedures was utilized for determining appropriate tolerance levels; see Appendix II for tolerance calculations. The petitioner should submit a revised section F reflecting the recommended tolerance for the *vegetable, tuberous and corm, subgroup 1C* and the correct commodity definitions as presented in Table 9.

No changes to the existing tolerances for livestock commodities are needed as a result of the proposed uses.

There are Canadian and Codex MRLs for residues of azoxystrobin and its (Z)-isomer for most of the requested crops. The Codex MRLs (JMPR Report 2008) are based on US field trials, except for subgroup 8-10A and 8-10B which were conducted in Europe. Even though the Codex MRLs are based on US field trials, there is a slight difference between MRLs of Codex/US due in part to the difference in the residue definition. The US residue definition includes both the predominant E isomer and the minor Z isomer. The Codex residue definition includes only the E isomer. The difference in Codex and US MRL estimates, based on the same data set, is based on the JMPR rounding procedures and the tendency to increase the estimate for small data sets.

The US and Codex MRLs are in harmony for subgroup 13-07A, strawberries, and sunflower seeds. The US and Codex MRLs are not in harmony for subgroup 13-07G; dragon-fruit (mango); onion, bulb dry and green; vegetable subgroup 8-10A; tuberous and corm vegetables subgroup 1C, and wasabi (herbs, fresh and dry).

HED recommends increasing the US MRLs for bushberry, subgroup 13-07B, cottonseed, citrus fruit, 10-10, fruit vine climbing 13-07F [grape], and pepper/eggplant 8-10B to harmonize with Codex.

The US and Canadian MRLs are in harmony on all proposed crops, except subgroup 13-07F, 13-07G, and cottonseed. There are no Canadian MRLs on cottonseed. Canadian MRLs were not established as subgroups for 13-07F and 13-07G and were established on grapes (3 ppm) and lowbush blueberries and ligonberries (subgroup 13-07B) at 3 ppm; US MRLs were established at 1 ppm for 13-07F and at 10 ppm for 13-07G. The current post-harvest use on vegetable tuberous and corm, subgroup 1C recommends increasing the established US MRL on vegetable tuberous and corm, subgroup 1C to 8 ppm, which is in agreement with the proposed Canadian MRL.

Citrus fruit:
The Codex MRL is based on field trials conducted in the USA. The MRL was estimated at 15 ppm using the post-harvest dip results with one and two applications on the smaller citrus fruits (lemon, tangerine, and mandarin). The highest residue was 8.8 ppm. The 2008 JMPR Report (General Consideration 2.7) indicates that statistical evaluation of the data with the NAFTA calculator produced an estimate of 12.3 mg/kg. JMPR decided upon a higher value because of the small size of the data set. The US MRL (10.0 ppm) was based on field trial data that received preharvest as well as post harvest dip treatments on grapefruit, orange, and lemon samples; highest residue was 9.18 ppm.

Berries and other small fruits:
The Codex MRL for berries and other small fruits except cranberry, grapes, and strawberry is based on field trials conducted in the USA (blackberry, raspberry, and blueberry). The estimated MRL is 5 ppm which is in harmony with US MRL for subgroup 13-07A.

For grapes and strawberries, the Codex MRL is based on field trials conducted in the USA. The Codex estimated MRLs were 2 ppm (1 ppm US) and 10 ppm, respectively; highest residues were 0.81 ppm for grapes and 4.5 ppm for strawberries. The 2008 JMPR Report (General Consideration 2.7) indicates that statistical evaluation of the data for grapes with the NAFTA calculator produced an estimate of 1.63 mg/kg, rounded to 2 mg/kg. The US tolerance is 1 ppm. A similar analysis for strawberries yielded an MRL estimate of 9.43 mg/kg, rounded to 10 mg/kg. The US strawberry MRL is in agreement with Codex MRL.

Mango
The Codex MRL is based on field trials conducted in the USA. The highest residue was 0.48 ppm; the MRL was estimated at 0.7 ppm. The 2008 JMPR Report (General Consideration 2.7) indicates that statistical evaluation of the data with the NAFTA calculator produced an estimate of 1.67 mg/kg, which JMPR discarded because of the small data set and the use of professional judgment. The US MRL was established at 2.0 ppm

Onion, bulb (dry) and green onion
The Codex MRL is based on field trials conducted in the USA which includes a trial with higher application rate (about 2x). The MRL was estimated at 10 ppm for bulb vegetables based on the result on spring onions; highest residue was 6.3 ppm. The 2008 JMPR Report (General Consideration 2.7) indicates that statistical evaluation of the data with the NAFTA calculator produced an estimate of 11.1 mg/kg, which JMPR decided to reduce to 10 mg/kg. The US MRL is established at 1 ppm for subgroup 3-07A and 7.5 ppm for subgroup 3-07B; highest residues were 0.67 and 6.9 ppm, respectively.

Vegetables Fruiting, subgroup 8-10A and 8-10B
The Codex MRL is based on field trials conducted on sweet pepper and tomatoes grown in an indoor environment in Europe. The data on sweet pepper and tomatoes were combined (n = 11). The maximum residue was 1.4 mg/kg on pepper. The 2008 JMPR Report (General Consideration 2.7) indicates that statistical evaluation of the data with the NAFTA calculator produced an estimate of 2.17 mg/kg. The MRL was estimated at 3 ppm for fruiting vegetables, other than cucurbits, except fungi and sweet corn. The US MRLs (0.2 tomatoes and 2.0 for group 8, except tomato) were based on trials conducted on tomatoes, bell peppers and non-bellpeppers; maximum residues were 0.18 and 0.40 and 0.92, respectively.

Root and tuber vegetables
The Codex MRL is based on field trials conducted on beetroot, carrot, and radish conducted in the USA. Results of these trials were combined and the highest residue was 0.45 ppm. The MRL was estimated at 0.7 ppm for root and tuber vegetables. The 2008 JMPR Report (General Consideration 2.7) indicates that statistical evaluation of the data with the NAFTA calculator produced an estimate of 0.57 mg/kg based on 15 trials. JMPR rounded the value up slightly. The US MRL was established for vegetable, root subgroup 1A at 0.5 ppm (based on beetroot, carrot, and radish) and vegetable tuberous and corm, subgroup 1C at 0.03 ppm (based on potato); highest residues were 0.46 and 0.02 ppm, respectively. MRL was also established for potato at 0.03 ppm.

Oilseeds (Cotton seed)
The Codex MRL is based on field trials conducted on cotton as in-furrow and foliar treatments conducted in the USA. The results were combined and the maximum residue was 0.54 ppm. The 2008 JMPR Report (General Consideration 2.7) indicates that statistical evaluation of the data with the NAFTA calculator produced an estimate of 0.51 mg/kg based on 12 trials. JMPR selected an MRL of 0.7 mg/kg. The US highest residue was 0.62 ppm; tolerance was established at 0.6 ppm.

Sunflower seed
The Codex MRL is based on field trials conducted on sunflower in the USA. The 2008 JMPR Report (General Consideration 2.7) indicates that statistical evaluation of the data with the NAFTA calculator produced an estimate of 0.31 mg/kg based on 6 trials. JMPR selected an MRL of 0.5 mg/kg and noted the unreliability of the statistical method because of the relatively small number of data points. The MRL was estimated at 0.5 ppm for sunflower seed; the Codex/US highest residue was 0.24 ppm. The US tolerance was established at 0.6 ppm.

Herbs (For Wasabi-extrapolation from subgroup 19A, fresh and dry)
The Codex MRL is based on field trials conducted on basil, mint, and parsley conducted in the USA (chive was not included since the residues were much lower). The highest residue was 48 ppm. The 2008 JMPR Report (General Consideration 2.7) indicates that statistical evaluation of the data with the NAFTA calculator produced an estimate of 52.3 mg/kg based on 7 trials. The MRL was estimated at 70 ppm for fresh herbs. The US MRL was estimated at 50 ppm for subgroup 19A, fresh; the highest residue on basil was 49 ppm.

Dried herbs
The Codex MRL is based on field trials conducted on basil, chives, and parsley conducted in the

USA (chive was not included since the residues were much lower). The highest residue was 235 ppm. The 2008 JMPR Report (General Consideration 2.7) indicates that statistical evaluation of the data with the NAFTA calculator produced an estimate of 297 (307) mg/kg based on 4 trials. The MRL was estimated at 300 ppm for dried herbs, except dry hops. The US MRL was estimated at 260 ppm for subgroup 19A, dried leaves based on dried basil (257 ppm).

Table 9. Tolerance Summary for Azoxystrobin

Commodity	Established Tolerance (ppm)	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
Onion, bulb, subgroup 3-07A	Onion, bulb 1.0	1.0	1.0	
Onion, green, subgroup 3-07B	Onion, green 7.5	7.5	7.5	
Vegetable, fruiting, subgroup 8-10A	Tomato 0.2	0.2	0.2	*Tomato subgroup 8-10A*
Vegetable, fruiting, subgroup 8-10B	Vegetable, fruiting, group 8, except tomato 2.0	2.0	3.0	*Pepper/eggplant subgoup 8-10B* Tolerance increase to harmonize with Codex.
Fruit, citrus, group 10-10	Fruit, citrus, group 10 10.0	10.0	15.0	Tolerance increase to harmonize with Codex.
Caneberry subgroup 13-07A	Caneberry subgroup 13A	5.0	5.0	
Bushberry subgroup 13-07B	Bushberry subgroup 13B, Juneberry, Lingonberry, and Salal at 3.0	3.0	5.0	Tolerance increase to harmonize with Codex.
Small fruit vine climbing, except fuzzy kiwifruit subgroup 13-07F	Grape 1.0	1.0	2.0	*Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F* Tolerance increase to harmonize with Codex.
Low growing berry subgroup 13-07G, except cranberry	Strawberry 10.0	10.0	10.0	*Berry, low growing, subgroup 13-07G, except cranberry*
Rapeseed subgroup 20A	Canola, seed 1.0	1.0	1.0	
Sunflower subgroup 20B	Safflower, seed and sunflower, seed 0.5	0.5	0.5	
Cottonseed subgroup 20C	Cotton, undelinted seed 0.6	0.6	0.7	Tolerance increase to harmonize with Codex.
Wasabi	Herb subgroup 19A, fresh leaves 50	50	50	*Wasabi, fresh*
Wasabi, dry	Herb subgroup 19A, dried leaves 260	Not proposed	260	*Wasabi, dry*

Dragon-fruit	Mango 2.0	2.0	2.0	
Vegetable, tuberous and corm, subgroup 1C	0.03	6.0	8.0	

References

DP#s: 218318 and 218448
Subject: PP No. 5F4541: New Chemical: Azoxystrobin (ICIA5504) in/on Grape RACs. Evaluation of Analytical Methods and Residue Data. CBTS Nos. 16051 & 16092.
From: J. Garbus
To: J. Bazuin/C. Giles-Parker
Dated: 3/19/96
MRIDs: 43678102-43678107, 43678193-43678195, 43678200-43678210 and 43694201-43694206

DP#s: 226232
Subject: PP No. 5F4541: New Chemical: Azoxystrobin (ICIA5504) in/on Grape Rac's. Chemical No. 128810. Revised Sections B and F and Additional Field Trial Residue
From: J. Garbus
To: D. McCall / B. Madden
Dated: 6/26/96
MRIDs: 440022-00 and 440022-01

DP#s: 230634, 230635, 230636, and 230637
Subject: PP#6F4762. Azoxystrobin. Permanent Tolerance Petition for Use on Bananas, Peaches, Peanuts, Tomatoes, and Wheat. Evaluation of Analytical Methodology and Residue Data. Chemical# 128810. CBTS#: None.
From: L. Kutney
To: C. Giles-Parker, J. Bazuin, and B. Madden
Dated: 4/25/97
MRIDs: 44058715-44058730, 44058732-44058736, and 44073203-44073205

DP#s: 248887 and 249671
Subject: PP#7F4864. Tolerance Petition for use of Azoxystrobin on Cucurbits. PP#8F4995. Tolerance Petition for use of Azoxystrobin on Bananas, Potatoes, and Stone Fruits.
From: D. Dotson, M. Doherty, and Y. Donovan
To: C. Giles-Parker/J. Bazuin
Dated: 10/14/98
MRIDs: 44319305, 44452303, 44595105, 44595109-44595111, 44595114, 44595116, 44613501, and 44613503

DP#:	251683
Subject:	Azoxystrobin. Conclusions of the Metabolism Assessment Review Committee at Meeting of 11/10/98.
From:	W. Wassell
To:	G. F. Kramer, MARC
Dated:	12/30/98
MRIDs:	None

DP#s:	249657 and 249668
Subject:	PP# 7F4864. Tolerance Petition for use of Azoxystrobin on Peanut Hay, Pistachios, Rice, Tree Nuts, and Wheat. PP# 8F4995. Tolerance Petition for use of Azoxystrobin on Canola.
From:	D. Dotson
To:	C. Giles-Parker/J. Bazuin
Dated:	1/25/99
MRIDs:	44319303, 44319304, 44319306-44319308, 44452303, 44595104-44595108, 44595113, 44595115 and 44613502

DP#:	254140
Subject:	Azoxystrobin on Various Commodities. IR-4 Proposal For Reduced Residue Chemistry Data Set.
From:	G. J. Herndon
To:	H. Jamerson/R. Forrest
Dated:	3/17/99
MRIDs:	44915206-32 and 44983101

DP#s:	260134
Subject:	PP#9F06058: Azoxystrobin. Evaluation of Residue Chemistry Data to Support Permanent Tolerances for Use of Azoxystrobin on Barley, Bulb Vegetables, Cilantro, Citrus Fruits, Corn, Cotton, Leafy Vegetables (except *Brassica*), Leaves of Root and Tuber Vegetables, Peanuts, Root and Tuber Vegetables, Soybeans, and Wild Rice; Higher Tolerances for the Fat and Meat Byproducts of Cattle, Goats, Horses, and Sheep; and, Apples (Inadvertent Residues).
From:	M. J. Nelson
To:	J. Bazuin/C. Giles-Parker
Dated:	09/06/2000
MRIDs:	449152-06 thru 449152-32; 449831-01

DP#s:	274312
Subject:	PP No. 5F4541: New Chemical: Azoxystrobin (ICIA5504) in/on Grape RACs. Evaluation of Analytical Methods and Residue Data. CBTS Nos. 16051 & 16092.
From:	G. Jeffrey Herndon
To:	S. Brothers/R. Forrest
Dated:	7/10/01
MRIDs:	45205604, 45205606, 45253901, and 45332502

DP#s:	279210
Subject:	Azoxystrobin. Registration on Caneberry. Summary of Analytical Chemistry and Residue Data.
From:	N. Dodd
To:	S. Brothers/R. Forrest
Dated:	6/19/02
MRID:	45522301

DP#s:	285603, 285606, 285607 and 285608
Subject:	PP#s 2E06489, 2E06495, 2E06375, and 2E06488. Azoxystrobin. IR-4 Permanent Tolerance Petitions with Field Trials on Globe Artichoke, Asparagus, Basil, Broccoli, and Cabbage. Summary of Analytical Chemistry and Residue Data.
From:	N. Dodd
To:	S. Brothers/R. Forrest
Dated:	1/22/03
MRIDs:	45544901, 45730101, 45730102, 45731301, and 45736301

DP#s:	283588 and 287062
Subject:	PP#9F06058 and ID#s 000100-01098 and 000100-01093. Azoxystrobin. Condition-of-Registration Data, Including Bridging Data from the 50 WDG Formulation to the 2.08 FIC Formulation on Spinach, Garden Beet, Green Onion and Celery; Storage Stability Data; and Limited Field Rotational Crop Data.
From:	N. Dodd
To:	J. Bazuin/C. Giles-Parker
Dated:	2/6/03
MRIDs:	45640301, 45640302, 45640304-46560307, and 45738101

DP#:	298114
Subject:	Azoxystrobin. Heritage Fungicide (EPA Reg. No. 100-1093. Condition-of-Registration Data: Limited Field Rotational Crop Data. Petition Number 9F6058.
From:	L. Cheng
To:	J. Bazuin/C. Giles-Parker
Dated:	12/20/05
MRIDs:	45872401

DP#s:	D312949, D312951, D312953, & D317291
Subject:	Azoxystrobin Use on Dill, Chive, Sunflowers, Canola, and Post-Harvest Citrus. Review of Analytical Methods and Residue Data. Petition #'s 3E6637, 3E6749, 4E6823, & 5E6916.
From:	W. Cutchin
To:	B. Madden/D. Rosenblatt
Dated:	1/23/06
MRIDs:	46006901, 46219201, 46046603, 46046604, 46046601, 46046602 & 46509101

DP#s:	328984
Subject:	Azoxystrobin. Uses on Foliage of Legume Vegetables, Group 7; Fruiting Vegetables, Group 8 (Except Tomato); Pea and Bean, Succulent and Dried Shelled (Except Soybeans), Subgroups 6B and 6C; and Nongrass Animal Feeds, Group 18. Summary of Analytical Chemistry and Residue Data. Petition Number 4E6823.
From:	W. Cutchin
To:	S. Jackson/D. Rosenblatt
Dated:	6/19/06
MRIDs:	46006901, 46219201, 46046603, 46046604, 46046601, 46046602 & 46509101

DP#s:	334571 and 340016
Subject:	Azoxystrobin. Petitions for the Establishment of Permanent Tolerances for New/Amended Uses on Non-grass Animal Feeds (Crop Group 18), Sorghum, Wheat, Cotton and Wild Rice. PP#s 6F7106 & 7F7198. Summary of Analytical Chemistry and Residue Data.
From:	W. Cutchin
To:	S. Piper and T. Kish/J. Bazuin
Dated:	3/12/08
MRIDs:	46924301-46924303, 47096401-47096402

Attachments:
Appendix I - International Residue Limit Status Sheet
Appendix II - Tolerance Assessment Calculations

Template Version September 2005

Appendix I - International Residue Limit Status Sheet.

Azoxystrobin (PC Code 128810; 10/31/2011)

Summary of US and International Tolerances and Maximum Residue Limits			
Residue Definition:			
US	Canada	Mexico[2]	Codex[3]
40 CFR 180. 507 Plants: sum of azoxystrobin, [methyl(E)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate], and the *Z*-isomer of azoxystrobin [methyl(Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3 methoxyacrylate]	(α*E*)-methyl 2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-α-(methoxymethylene) benzeneacetate, including the isomer (*Z*)-methyl 2-[[6-(2-cyanophenoxy)-4-pyrimidinyl] oxy]-α-(methoxymethylene)benzeneacetate		Azoxystrobin. The residue is fat soluble.

Commodity[1]	*Tolerance (ppm) /Maximum Residue Limit (mg/kg)*			
	US	Canada	Mexico[2]	Codex[3]
Berry, low growing, subgroup 13-07G, except cranberry	10.0	3.0 lowbush blueberries, lingonberries		5 berries and other small fruits, except cranberry, grapes and strawberry 10 strawberry
Bushberry subgroup 13-07B	5.0	3.0 bushberries (crop subgroup 13-07B) aronia berries, blueberries, buffalo currants, Chilean guava, currants, elderberries, European barberries, gooseberries, highbush blueberries, highbush cranberries, honeysuckle, huckleberries, jostaberries, lingonberries, lowbush blueberries, native currants, salal berries saskatoon berries (juneberries), sea buckthorn		5 berries and other small fruits, except cranberry, grapes and strawberry
Caneberry subgroup 13-07A	5.0	5.0 caneberries (crop subgroup 13-07A) blackberries, loganberries, raspberries, wild raspberries		5 berries and other small fruits, except cranberry, grapes and strawberry
Cottonseed subgroup 20C	0.7			0.7 cotton seed
Dragon-fruit	2.0	2 mangoes		0.7 mango

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US		Canada	Mexico[2]	Codex[3]
Fruit, citrus, group 10-10	15.0	10 citrus fruits ; Australian desert limes, Australian finger limes, Australian round limes, Brown River finger limes, calamondins, citrus citrons, citrus hybrids, grapefruits, Japanese summer grapefruits, kumquats, lemons, limes, Mediterranean mandarins, mount White limes, new Guinea wild limes, oranges, pummelos, Russell River limes, Satsuma mandarins, sweet limes, tachibana oranges, Tahiti limes, tangelos, tangerines, tangors, trifoliate oranges, uniq fruits		15 citrus fruits
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	2.0	3 grapes		2 grapes
Onion, bulb, subgroup 3-07A	1.0	1.0 dry bulb onions		10 bulb vegetables
Onion, green, subgroup 3-07B	7.5	7.5 green onions		
Pepper/eggplant subgroup 8-10B	3.0	2.0 bell peppers, eggplants, non-bell peppers, pepinos, pepper hybrids,		3 fruiting vegetables other than cucurbits except mushrooms and sweet corn; 30 peppers chili dried
Rapeseed subgroup 20A	1.0	1.0 rapeseeds (canola)		
Sunflower subgroup 20B	0.5	0.5 sunflower seeds		0.5 sunflower seed
Tomato subgroup 8-10A	0.2	2.0 ground cherries, tomatillos 0.2 tomatoes 0.6 tomato paste		3 fruiting vegetables other than cucurbits except mushrooms and sweet corn
Vegetable, tuberous and corm, subgroup 1C	8.0	8.0 vegetable, tuberous and corm, subgroup 1C (proposed) 0.03 potatoes		1 root and tuber vegetables
Wasabi, fresh	50	50 Herbs (crop subgroup 19A; fresh leaves)		70 herbs
Wasabi, dry	260	260 Herbs (crop subgroup 19A; dried leaves)		300 dried herbs (except hops (dry))
Completed: M. Negussie; 10/31/2011				

[1] Includes only commodities of interest for this action. Tolerance values should be the HED recommendations and not those proposed by the applicant.

[2] Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

[3] * = absent at the limit of quantitation; Po = postharvest treatment, such as treatment of stored grains. PoP = processed postharvest treated commodity, such as processing of treated stored wheat. (fat) = to be measured on the fat portion of the sample. MRLs indicated as proposed have not been finalized by the CCPR and the CAC.

Appendix II. Tolerance Assessment Calculations.

For the potato postharvest use, the *OECD* statistical calculation procedures were used for calculating the recommended tolerance. As specified in the OECD document, the average residue value was used. The rounding procedures specified in the OECD guideline were also used.

The datasets used to establish a tolerance for combined residues of azoxystrobin and its *Z*-isomer for the potato postharvest use consisted of field trial data representing application rates of 4 g ai/2000 lb potatoes (0.009 lb ai/2000 lb potatoes) at a 0-day PHI.

The average residue values for the potato postharvest use which were used to calculate the tolerance are provided in Table II-1 and these values were entered in the OECD statistical calculation procedures. Using the OECD statistical calculation procedures, the recommended tolerance is 8 ppm (Figure II-1-3). The recommended tolerance (8 ppm) is higher than the proposed tolerance (6 ppm).

Table II-1. Residue data used to calculate tolerance for azoxystrobin on potato postharvest.		
Regulator:	EPA	
Chemical:	Azoxystrobin	
Crop:	Potato postharvest	
PHI:	0-day	
App. Rate:	4 g ai/2000 lb potatoes (0.009 lb ai/2000 lb potatoes)	
Submitter:	IR-4	
MRID Citation:	MRID 48437101	
	Average Combined Residues of Azoxystrobin and its *Z*-Isomer (ppm)	
	2.230	
	1.420	
	1.004	
	3.590	
	3.800	
	1.150	
	3.550	
	2.280	

Figure II- 1. Tolerance spreadsheet summary of azoxystrobin field trial data for potato postharvest.

Azoxystrobin
Potato-post harvest
EPA
4 g ai/2000 lb potatoes; PHI=0

Total number of data (n)	8
Percentage of censored data	0%
Number of non-censored data	8
Lowest residue	1.004
Highest residue	3.800
Median residue	2.255
Mean	2.378
Standard deviation (SD)	1.147
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue	3.800
- Mean + 4 SD	6.966
- CF x 3 Mean	7.134
Unrounded MRL	7.134
Rounded MRL	8

Primary Evaluator	Meheret Negussie, Chemist Risk Assessment Branch III Health Effects Division (7509P) Meheret Negussie	Date: 01/04/2012
Peer Reviewer	Melissa Watchorn, Evaluation Officer Minor Use Assessment Section (MUAS) Health Evaluation Directorate (HED) Pest Management Regulatory Agency (PMRA)	Date: Jan 6, 2012
Approved by	Jennifer Selwyn, Section Head Minor Use Assessment Section (MUAS) Health Evaluation Directorate (HED) Pest Management Regulatory Agency (PMRA)	Date: Jan 13, 2012
Approved by	Leung Cheng, Senior Chemist Risk Assessment Branch III Health Effects Division (7509P) Leung Cheng	Date: 01/05/2012

This DER was originally prepared under contract by Versar, Inc. (6850 Versar Center, Springfield, VA 22151; submitted (7/22/2011). The DER has been reviewed by HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORTS:

MRID No. 48437101. PMRA No. 2044028. Hampton, M. (2011) Azoxystrobin + Fludioxonil + Difenoconazole: Magnitude of the Residue on Potato Following Post-Harvest Treatment: Final Report. Report Number: IR-4 PR No. 09860 and TK0003297. Unpublished study prepared by Syngenta Crop Protection, Inc. 1011 p.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. submitted residue data for difenoconazole, azoxystrobin, and fludioxonil on potatoes following post-harvest treatment. This DER pertains to the magnitude of residues of azoxystrobin and the Z-isomer metabolite R230310 only; difenoconazole and fludioxonil results are reported in separate DERs. Five post-harvest trials were conducted in the United States and Canada in 2009-2010 in the North American Free Trade Agreement (NAFTA) Growing Zones 1 (ME; 1 trial), 5A (WI; 1 trial), 5 (ON; 1 trial), and 11 (WA and ID; 2 trials).

Potatoes were grown on-site by the trial personnel in the US trials and were obtained from a commercial grower in the Canadian trial. Samples of mature potato tubers were harvested from all trials, placed in on-site storage for ~1-4 months, and then treated with a spray mixture containing a 3.00 lb ai/gal (360 g a.i./L) difenoconazole flowable suspension (FS) formulation, a 2.09 lb ai/gal (250 g a.i./L) azoxystrobin soluble concentrate (SC) formulation, and a 1.92 lb ai/gal (230 g a.i./L) fludioxonil SC formulation.

In all trials, the test mixture was applied as a post-harvest treatment spray directed to tubers falling from a conveyor belt or moving along a roller table (TRT 02). At the ID trial, three additional treatment scenarios were included: surface spray directed to tubers on a tarp (TRT 03); spray directed to tubers in a spray chamber (TRT 04); and spray directed to tubers on a brush table (TRT 05). For each treatment, azoxystrobin was applied at a rate of 0.0089-0.0099 lb ai/2000 lb potatoes (4.0309-4.5105 g ai/2000 lb potatoes [0.44-0.50 g a.i./100 kg potatoes) using water as the carrier; the delivery rate was 0.22-0.54 gal/2000 lb potatoes (0.09-0.23 L/100 kg potatoes).

Samples of potatoes from each trial site were collected after the test substance had dried on the day of application [0 days after application (DAA)]. At three sites (WA, ON, and ID), additional treated samples were collected and placed in storage for 13-14, 30-32, 59-61, and/or 231 days after application to generate residue decline data.

Potato samples were analyzed for residues of azoxystrobin and its metabolite R230310 using high pressure liquid chromatography/tandem mass spectrometry (LC/MS/MS); modified Syngenta Analytical Method RAM 305/03 (MRID# 47096401; PMRA # 2044022). This method has been reviewed previously and deemed acceptable for data gathering. The limit of quantitation (LOQ; determined as the lowest limit of method validation, LLMV) was 0.01 ppm for both analytes. The method was verified prior to and in conjunction with sample analyses and is considered adequate based on acceptable method validation and concurrent recovery data. The fortification levels used in method validation and concurrent method recovery were adequate to bracket expected residue levels.

Potato samples were stored at <-10 °C prior to analysis for a maximum of 258 days (8.5 months). All samples were analyzed within 0 to 3 days of extraction. Adequate storage stability data are available indicating that residues of azoxystrobin and R230310 are stable at <-15 °C for at least 24 months in/on soybean meal, corn grits, carrot root, leaf lettuce, grain sorghum forage, orange oil, and orange juice (MRID 45738101; PMRA # 956496). Additionally, data on file indicate residues of azoxystobin and R230310 are stable for up to 2 years in cucumbers, apples, grapes, peaches, peanuts, pecans, rapeseed, tomatoes, bananas, and wheat grain (MRID 44452303; PMRA # 1191031). These data may be translated to potatoes to validate the storage durations and conditions of azoxystrobin and R230310 for the potato field trial samples (OECD Guidelines for the Testing of Chemicals, Test No. 506, Adopted 16 October, 2007).

Residues of azoxystrobin were 0.992-4.15 ppm (per trial average residues were 0.994-3.79 ppm) in/on potatoes collected 0 DAA following one post-harvest spray treatment application of azoxystrobin formulated as a 2.09 lb ai/gal (250 g a.i./L) SC at a total seasonal rate of 0.0089-0.0099 lb ai/2000 lb potatoes (0.44-0.50 g a.i./100 kg potatoes). Residues of R230310 were all

<LOQ (0.01 ppm). All application methods (directed spray to tubers on a conveyor belt, roller table, stationary surface, spray chamber, or brush table) resulted in similar residue levels.

In the ON decline trial, residues of azoxystrobin remained constant; residues of azoxystrobin from the WA and ID trials generally decreased with increasing DAA. Residues of R230310 were <LOQ at each sampling interval; therefore, residue decline could not be assessed for the metabolite.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP# 390152, and in Canada's forthcoming Evaluation Report.

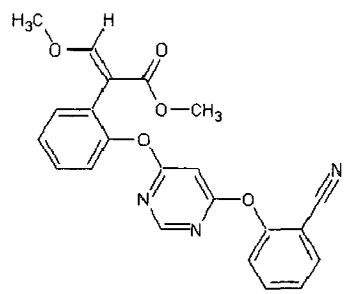
COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance, and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Azoxystrobin is a broad spectrum fungicide for control of many plant diseases. It has the same biochemical mode of action as the naturally occurring strobilurins and is structurally related to them. Azoxystrobin is a ß-methoxyacrylate. It is in the same chemical class as trifloxystrobin. Azoxystrobin acts by inhibiting electron transport.

TABLE A.1. Test Compound Nomenclature.

Compound	Chemical Structure
	
Common name	Azoxystrobin
Company experimental name	ICIA5504
IUPAC name	methyl (2*E*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
CAS name	methyl (α*E*)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-α-(methoxymethylene)-benzeneacetate
CAS #	131860-33-8
End-use product/(EP)	Azoxystrobin SC is a suspension concentrate formulation containing 2.09 lb ai/gal (250 g a.i./L) azoxystrobin (Azoxystrobin 250 SC)

40

TABLE A.2. Physicochemical Properties of the Technical Grade Azoxystrobin.

Parameter	Value	Reference[1]
Melting point/range	114-116°C	43678105
pH	6.4	43678105
Density	1.25 g/cm^3	43678105
Water solubility (mg/L at 20°C)	solvent / solubility water, pH 5.2: 6.7 mg/L water, pH 7: 6.7 mg/L water, pH 9.2: 5.9 mg/L	43678105
Solvent solubility (mg/L at 20°C)	solvent / solubility n-hexane: 0.057 mg/mL methanol: 20 mg/mL ethyl acetate: 130 mg/mL toluene: 55 mg/mL acetone: 86 mg/mL dichloromethane: 400 mg/mL	43678105
Vapor pressure at 25°C	1.1 x 10^{-13} kPa = 8.2 x 10^{-13} mg Hg	43678105
Dissociation constant (pK_a)	Not dissociable	43678105
Octanol/water partition coefficient Log(K_{OW})	log P_{Ow} = 2.5	43678105
UV/visible absorption spectrum	Not available	

[1]DP#s 218318 and 218448, 3/19/96, J. Garbus

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Five post-harvest field trials were conducted in the United States and Canada in 2009-2010 in NAFTA Growing Zones 1 (ME; 1 trial), 5A (WI; 1 trial), 5 (ON; 1 trial), and 11 (WA and ID; 2 trials).

Potatoes were grown on-site by the trial personnel in the US trials and were obtained from a commercial grower in the Canadian trial. Samples of mature potato tubers were harvested from all trials and placed in on-site storage (cold storage or at 43-58 °F [6-14 °C]) for approximately 1-4 months prior to post-harvest treatment. Meteorological data were not presented. However, soil characterization and meteorological data are not relevant to the study since the applications were made following harvest under (indoor) controlled conditions. The petitioner indicated that in the ME trial, June and July were the wettest months in recorded history and August was the driest. In the ON trial, temperatures were below normal and precipitation amounts were above normal. Temperature and precipitation data were reported to be within normal parameters in the remaining trials.

Prior to application, potatoes collected from the WA trial site were washed and dried; excess dirt was removed from potatoes collected from the ME trial site. In all trials, a SC formulation containing 2.09 lb ai/gal (250 g a.i./L) azoxystrobin was applied as a post-harvest treatment spray directed to tubers falling from a conveyor belt or moving along a roller table (TRT 02). At the ID trial, three additional treatment scenarios were included: tubers were placed close together on a tarp, sprayed, allowed to dry, turned over, and sprayed again (TRT 03); placed close together inside a spray chamber, sprayed, allowed to dry, turned over, and sprayed again (TRT 04); and placed on a brush table that rolled the potatoes under the spray (TRT 05). For each treatment, azoxystrobin was applied at a rate of 0.0089-0.0099 lb ai/2000 lb potatoes (4.0309-4.5105 g ai/2000 lb potatoes [0.44-0.50 g a.i./100 kg potatoes]) using water as the carrier; the delivery rate was 0.22-0.54 gal/2000 lb potatoes (0.09-0.23 L/100 kg potatoes).

Samples of potato tubers were collected from all trials following the post-harvest treatment after the test substance had dried (DAA 0). Samples were collected from the WA and ON trials at 0, 13-14, 31-32, and 59-61 days after the last application to generate residue decline data. Residue decline data were also generated at the ID trial site by collecting samples at 0, 30, and 231 days after application of the test substance.

Trial conditions are presented in Table B.1.1. The study use pattern is presented in Table B.1.2, and the crop varieties grown are identified in Table C.3.

TABLE B.1.1 Trial Site Conditions.

Trial Identification: City, State/Province, Country; Year (Trial No.)	Soil characteristics			
	Type	%OM	pH	CEC meq/100 g
Prosser, WA, USA; 2009 (09-WA32)	Sandy clay to silt loam	4.88	6.10	11.67
Hancock, WI, USA; 2009 (09-WI19)	Sand	0.8	6.8	4
Corinth, ME, USA; 2009 (09-ME04)	NR	5.1	6.2	7.6
Delhi, ON, Canada; 2010 (09-ON14)	NR	NR	NR	NR
Kimberly, ID, USA; 2009 (09-ID19)	Silt loam	1.59	8.2	18.6

NR= Not reported

TABLE B.1.2. Study Use Pattern.

Location (City, State/Province, Country; Year) Trial ID	EP[1]	Treatment No.	Application Information					Tank Mix/ Adjuvants
			Method; Timing	Delivery Rate (gal/2000 lb) [L/100 kg]	RTI (days)	Total Rate		
						g a.i./ 2000 lb	lb a.i./ 2000 lb [g a.i./100 kg]	
Prosser, WA, USA; 2009 (09-WA32)	SC	02	Spray directed to tubers falling from conveyor belt; Post-harvest	0.54 [0.23]	-	4.1050	0.0090 [0.45]	-
Hancock, WI, USA; 2009 (09-WI19)	SC	02	Spray directed to tubers falling from conveyor belt; Post-harvest	0.52 [0.22]	-	4.1947	0.0092 [0.46]	-
Corinth, ME, USA; 2009 (09-ME04)	SC	02	Spray directed to tubers falling from conveyor belt; Post-harvest	0.22[2] [0.09]	-	4.5105	0.0099 [0.50]	-
Delhi, ON, Canada; 2010 (09-ON14)	SC	02	Spray directed to tubers moving along roller table; Post-harvest	0.50 [0.21]	-	4.0473	0.0089 [0.45]	-
Kimberly, ID, USA; 2009 (09-ID19)	SC	02	Spray directed to tubers falling from conveyor belt; Post-harvest	0.50 [0.21]	-	4.0966	0.0090 [0.45]	-
		03	Spray directed to tubers on tarp; Post-harvest	0.50 [0.21]	-	4.0997	0.0090 [0.45]	-

TABLE B.1.2. Study Use Pattern.

Location (City, State/Province, Country; Year) Trial ID	EP[1]	Treatment No.	Application Information					Tank Mix/ Adjuvants
			Method; Timing	Delivery Rate (gal/2000 lb) [L/100 kg]	RTI (days)	Total Rate		
						g a.i./ 2000 lb	lb a.i./ 2000 lb [g a.i./100 kg]	
		04	Spray directed to tubers in spray chamber; Post-harvest	0.50 [0.21]	-	4.0309	0.0089 [0.44]	-
		05	Spray directed to tubers on brush table; Post-harvest	0.50 [0.21]	-	4.0850	0.0090 [0.45]	-

[1] EP = End-use Product; suspension concentrate (SC) formulation containing 2.09 lb azoxystrobin/gal (250 g azoxystrobin/L).
[2] A controlled droplet applicator (CDA) was used to spray the potatoes as they fell off the conveyor belt. The protocol called for a pressure of 30-90 psi. The pressure of the pump on the CDA was unknown (no gauge or means of measuring). The CDA is a commercial unit and often used on commercial farms. These sprayers use less solution to get the same coverage due to the very small droplet size.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Regions	Potato		
	Submitted	Requested[1,2]	
		Canada[3]	U.S.[4]
1	1	--	2/2
1A	--	--	--
2	--	--	1/1
3	--	--	1/1
4	--	--	--
5	1	--	4/2
5A	1	--	--
5B	--	--	--
6	--	--	--
7	--	--	--
7A	--	--	--
8	--	--	--
9	--	--	1/1
10	--	--	1/1
11	2	--	6/4
12	--	--	--
13	--	--	--
14	--	--	--
15	--	--	--
16	--	--	--
17	--	--	--
18	--	--	--
19	--	--	--
20	--	--	--
21	--	--	--
Total	5	2	16/12

[1] As per the OECD Guideline for the Testing of Chemicals – Crop Field Trial (9/7/2009), the number of post-harvest trials on a commodity should be at least four, taking into consideration the application techniques, storage facilities, and packing materials used.
[2] As per the Commission of the European Communities Working Document: Guidelines on Comparability, Extrapolation, Group Tolerances and Data Requirements for Setting MRLs (12/6/2001), residues arising from post-harvest treatments are expected to have an inherently higher level of homogeneity and not to be affected by climatic conditions. Differences in residue level may be associated with different store types and in homogeneous distribution of the applied plant protection product within the stored products. With regard to the required number of trials, post-harvest treatments were therefore considered as a "single zone world wide."
[3] According to DIR98-02 (Section 9), two trials (4 treated samples per trial) are required to support post-harvest uses. Trial locations are not specified for post-harvest uses.
[4] As per Table 5 of 860.1500 for potato; the second number reflects a 25% reduction in the number of field trials allowed for the crop as a representative commodity in support of a crop group/subgroup tolerance or when application results in no quantifiable residues.

B.2. Sample Handling and Preparation

At all test sites, six untreated and treated potato samples were collected at 0 DAA (after the test substance had dried); however, only duplicate samples were shipped to the analytical laboratory. Three sites collected additional treated decline samples at 13-14, 30-32, 59-61, and/or 231 days after application to generate residue decline data. The treated samples (consisting of ~14 tubers) were collected and placed in frozen storage at the field trials within ~3 hours after collection. Samples were shipped after collection within 1-169 days by ACDS freezer truck or by FedEx overnight service to Morse Labs (Sacramento, CA) for residue analysis. Samples were maintained frozen (-20 ± 5 °C) at the analytical laboratory prior to homogenization and analysis. In preparation for analysis, the potato samples were ground in a Hobart food grinder equipped with a 1/8 inch plate or a Robot Coupe Vertical Cutter using dry ice to a homogeneous consistency.

B.3. Analytical Methodology

Samples of potatoes were analyzed for residues of azoxystrobin and its metabolite R230310 using a LC-MS/MS method modified from Syngenta Analytical Method RAM 305/03 (MRID# 47096401; PMRA # 2044022). The method has been reviewed previously and deemed acceptable for data gathering. The modifications to the reference method were minor, and did not include changes to extraction solvents, cleanup procedures, or quantitation methods. A brief description of the method was included in the submission.

Residues of azoxystrobin and R230310 in potato samples were extracted with acetonitrile/water (90:10, v:v) and centrifuged. Aliquots of the extracts were cleaned up using solid phase extraction and analyzed using LC-MS/MS detection.

The LOQ (determined as the LLMV) was 0.01 ppm for each analyte; the limit of detection (LOD) was not reported.

The method was validated prior to and in conjunction with the field trial samples.

C. RESULTS AND DISCUSSION

Five post-harvest trials were conducted on potatoes in the US and Canada in 2009 and 2010.

Sample storage conditions and durations for samples of potatoes are reported in Table C.2. Azoxystrobin and metabolite R230310 samples were stored at <-10 °C prior to analysis for 10-258 days (0.3-8.5 months). All samples were analyzed within 0 to 3 days of extraction. Adequate storage stability data are available indicating that residues of azoxystrobin and R230310 are stable at <-15 °C for at least 24 months in/on soybean meal, corn grits, carrot root, leaf lettuce, grain sorghum forage, orange oil, and orange juice (refer to DER for MRID No. 45738101; PMRA # 956496). Additionally, data on file indicate residues of azoxystobin and R230310 are stable for up to 2 years in cucumbers, apples, grapes, peaches, peanuts, pecans, rapeseed, tomatoes, bananas, and wheat grain (PMRA # 1191031). These data may be translated to potatoes to validate the storage durations and conditions for the samples analyzed as part of the current study (OECD Guidelines for the Testing of Chemicals, Test No. 506, Adopted 16 October, 2007).

Concurrent method recovery data and method validation data for the LC/MS/MS method is presented in Table C.1. For concurrent method recovery and method validation recovery, potato samples were fortified at 0.01-10 ppm with azoxystrobin and R230310. Average recoveries were within the acceptable range of 70-120%. The method is considered adequate based on concurrent recovery and method validation data. The fortification levels used in concurrent method recovery were adequate to bracket expected residue levels.

Apparent residues of azoxystrobin and R230310 were each below the LOQ (<0.01 ppm) in/on all samples of untreated potatoes. Additionally, there were no interferences reported in the control samples.

Residue data from the potato field trials are reported in Table C.3. A summary of residue data for potato is presented in Table C.4. Residues of azoxystrobin were 0.992-4.15 ppm (per trial average residues were 0.994-3.79 ppm) in/on potatoes collected 0 DAA following one post-harvest spray treatment application of azoxystrobin formulated as a 2.09 lb ai/gal (250 g a.i./L) SC at a total seasonal rate of 0.0089-0.0099 lb ai/2000 lb potatoes (0.44-0.50 g a.i./100 kg potatoes). Residues of R230310 were all <LOQ (0.01 ppm). All application methods (directed spray to tubers on a conveyor belt, roller table, stationary surface, spray chamber, or brush table) resulted in similar residue levels.

In the ON decline trial, residues of azoxystrobin remained constant; residues of azoxystrobin from the WA and ID trials generally decreased with increasing DAA. Residues of R230310 were <LOQ at each sampling interval; therefore, residue decline could not be assessed for the metabolite. Decline data are summarized in Table C.5.

TABLE C.1. Summary of Method and Concurrent Recoveries of Azoxystrobin and its Metabolite R230310 from Potato.

Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)[1]	Mean ± Std. Dev. (%)[2]
Method Validation Recoveries					
Potato	Azoxystrobin	0.01	3	98, 89, 99	95 ± 5.5
		0.1	3	116, 115, 117	116 ± 1.0
		1.0	3	72, 90, 100	87 ± 14
		10	3	73, 76, 102	84 ± 16
	R230310	0.01	3	105, 96, 114	105 ± 9.0
		0.1	3	119, 117, 120	119 ± 1.5
		1.0	3	73, 88, 95	85 ± 11
		10	3	70, 77, 102	83 ± 17
Concurrent Recoveries					
Potato	Azoxystrobin	0.01	6	101, 98, 111, 107, 95, 89	100 ± 8.0
		1.0	4	94, 100, 92, 97	96 ± 3.5
		10	2	118, 87	103

TABLE C.1. Summary of Method and Concurrent Recoveries of Azoxystrobin and its Metabolite R230310 from Potato.

Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)[1]	Mean ± Std. Dev. (%)[2]
	R230310	0.01	6	98, 103, 117, 99, 100, 94	102 ± 8.0
		1.0	4	96, 98, 93, 94	95 ± 2.2
		10	2	115, 89	102

[1] The concurrent recoveries were corrected for apparent residues in the unfortified control samples.
[2] Standard deviations were calculated only for fortification levels having ≥3 samples.

TABLE C.2. Summary of Storage Conditions.

Matrix	Analyte	Storage Temperature (°C)	Actual Storage Duration[1]	Limit of Demonstrated Storage Stability
Potato	Azoxystrobin	<-10	10-258 days (0.3-8.5 months)	Adequate storage stability data are available indicating that residues of azoxystrobin and R230310 are stable at <-15 °C for at least two years in/on soybean meal, corn grits, carrot root, leaf lettuce, grain sorghum forage, orange oil, and orange juice.[2] Additionally, data on file indicate residues of azoxystobin and R230310 are stable for up to 2 years in cucumbers, apples, grapes, peaches, peanuts, pecans, rapeseed, tomatoes, bananas, and wheat grain.[3]
	R230310			

[1] Interval from sampling to analysis. Extracts were stored 0-3 days prior to analysis.
[2] Refer to DER for MRID 45738101 (DP# 287062; PMRA # 956496).
[3] Refer to DER for MRID 44452303; PMRA # 1191031.

TABLE C.3. Residue Data from Potato Field Trials with Azoxystrobin.

Trial ID (City, State; Year)	Zone	Crop/ Variety	Comm.	Total Rate g a.i./ 2000 lb	Total Rate lb a.i./ 2000 lb [g a.i./100 kg]	DAA	App. Method	Residues (ppm)[1] [Average] Azoxystrobin	Residues (ppm)[1] [Average] R230310	Residues (ppm)[1] [Average] Total Residues
Prosser, WA, USA; 2009 (09-WA32)	11	Potato/ Russett Burbank	Tubers	4.1050	0.0090 [0.45]	0	Conveyor Belt [TRT 02]	2.26 2.17 [2.22]	<0.01 <0.01 [<0.01]	2.27 2.18 [<2.23]
						13		2.52 1.60[2] [2.06]	<0.01 <0.01 [<0.01]	2.53 1.61 [<2.07]
						32		2.58[2] 1.62 [2.10]	<0.01 <0.01 [<0.01]	2.59 1.63 [<2.11]
						61		1.51 1.39 [1.45]	<0.01 <0.01 [<0.01]	1.52 1.40 [<1.46]
Hancock, WI, USA; 2009 (09-WI19)	5A	Potato/ Russett Burbank	Tubers	4.1947	0.0092 [0.46]	0	Conveyor Belt [TRT 02]	1.45 1.37 [1.41]	<0.01 <0.01 [<0.01]	1.46 1.38 [<1.42]
Corinth,	1	Potato/	Tubers	4.5105	0.0099	0	Conveyor	0.992	<0.01	1.002

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TABLE C.3. Residue Data from Potato Field Trials with Azoxystrobin.

Trial ID (City, State; Year)	Zone	Crop/ Variety	Comm.	Total Rate		DAA	App. Method	Residues (ppm)[1] [Average]		
				g a.i./ 2000 lb	lb a.i./ 2000 lb [g a.i./100 kg]			Azoxystrobin	R230310	Total Residues
ME, USA; 2009 (09-ME04)		Frito Lay 1533			[0.50]		Belt [TRT 02]	0.995 [0.994]	<0.01 [<0.01]	1.005 [<1.004]
Delhi, ON, Canada; 2010 (09-ON14)	5	Potato/ AC Chaleur	Tubers	4.0473	0.0089 [0.45]	0	Roller Table [TRT 02]	3.50 3.66 [3.58]	<0.01 <0.01 [<0.01]	3.51 3.67 [<3.59]
						14		4.75 4.51 [4.63]	<0.01 <0.01 [<0.01]	4.76 4.52 [<4.64]
						31		4.17 4.14 [4.16]	<0.01 <0.01 [<0.01]	4.18 4.15 [<4.17]
						59		4.34 4.25 [4.30]	<0.01 <0.01 [<0.01]	4.35 4.26 [<4.31]
Kimberly, ID, USA; 2009 (09-ID19)	11	Potato/ Russett Burbank	Tubers	4.0966	0.0090 [0.45]	0	Conveyor Belt [TRT 02]	4.15 3.42 [3.79]	<0.01 <0.01 [<0.01]	4.16 3.43 [<3.80]
						30		1.51 1.46 [1.49]	<0.01 <0.01 [<0.01]	1.52 1.47 [<1.50]
						231		0.752 0.435 [0.594]	<0.01 <0.01 [<0.01]	0.753 0.436 [<0.595]
				4.0997	0.0090 [0.45]	0	Surface [TRT 03]	1.22 1.05 [1.14]	<0.01 <0.01 [<0.01]	1.23 1.06 [<1.15]
				4.0309	0.0089 [0.44]	0	Spray Chamber [TRT 04]	3.57 3.50 [3.54]	<0.01 <0.01 [<0.01]	3.58 3.51 [<3.55]
				4.0850	0.0090 [0.45]	0	Brush Table [TRT 05]	2.31 2.23 [2.27]	<0.01 <0.01 [<0.01]	2.32 2.24 [<2.28]

[1] The validated LOQ was 0.01 ppm for each analyte. DAA = Days after application. Per trial averages are calculated using the LOQ for all residues reported as <LOQ. Total residues are the sum of azoxystrobin and R230310.
[2] The study report noted that replicates appear to be switched; however, analyses were confirmed.

TABLE C.4. Summary of Residue Data from Potato Crop Field Trials with Azoxystrobin.

Commodity	Analyte	Total App. Rate		DAA	Residue Levels (ppm)[1]							
		g a.i./ 2000 lb	lb a.i./ 2000 lb [g a.i./100 kg		n	Sample Min.	Sample Max.	LAFT[3]	HAFT[3]	Median	Mean	Std. Dev.[4]
TRT 02 (Conveyor Belt or Roller Table)												
Potato	Azoxystrobin	4.0473-	0.0089-	0	10	0.992	4.15	0.994	3.79	2.22	2.40	1.20

TABLE C.4. Summary of Residue Data from Potato Crop Field Trials with Azoxystrobin.

Commodity	Analyte	Total App. Rate		DAA	Residue Levels (ppm)[1]							
		g a.i./ 2000 lb	lb a.i./ 2000 lb [g a.i./100 kg		n	Sample Min.	Sample Max.	LAFT[3]	HAFT[3]	Median	Mean	Std. Dev.[4]
tubers	R230310	4.5105	0.0099 [0.45-0.50]		10	<0.01	<0.01	0.01	0.01	0.01	0.01	N/A
	Total Residues				10	<1.002	<4.16	1.004	3.80	2.23	2.41	1.20
TRT 03 (Surface)/Stationary												
Potato tubers	Azoxystrobin	4.0997	0.0090 [0.45]	0	2	1.05	1.22	1.14	1.14	N/A	N/A	N/A
	R230310				2	<0.01	<0.01	0.01	0.01	N/A	N/A	N/A
	Total Residues				2	<1.06	<1.23	1.15	1.15	N/A	N/A	N/A
TRT 04 (Spray Chamber)												
Potato tubers	Azoxystrobin	4.0309	0.0089 [0.44]	0	2	3.50	3.57	3.54	3.54	N/A	N/A	N/A
	R230310				2	<0.01	<0.01	0.01	0.01	N/A	N/A	N/A
	Total Residues				2	<3.51	<3.58	3.55	3.55	N/A	N/A	N/A
TRT 05 (Brush Table)												
Potato tubers	Azoxystrobin	4.0850	0.0090 [0.45]	0	2	2.23	2.31	2.27	2.27	N/A	N/A	N/A
	R230310				2	<0.01	<0.01	0.01	0.01	N/A	N/A	N/A
	Total Residues				2	<2.24	<2.32	2.28	2.28	N/A	N/A	N/A
Combined Treatments												
Potato tubers	Azoxystrobin	4.0309-4.5105	0.0089-0.0099 [0.44-0.50]	0	16[1]	0.992	4.15	--	--	2.25	2.37	1.12
					8[2]	--	--	0.994	3.79	2.25	2.37	1.15
	R230310				16[1]	<0.01	<0.01	--	--	0.01	0.01	N/A
					8[2]	--	--	0.01	0.01	0.01	0.01	N/A
	Total Residues				16[1]	<1.002	<4.16	--	--	2.26	2.38	1.12
					8[2]	--	--	1.004	3.80	2.25	2.37	1.15

[1] n = no. of samples. For calculation of median, mean, and standard deviation, the LOQ (0.01 ppm) was used for any results reported as <LOQ in Table C.3.
[2] n = no. of field trials; statistical calculations are based on per-trial average values.
[3] LAFT = lowest-average-field-trial; HAFT = highest-average-field-trial.
[4] N/A = Not applicable.

TABLE C.5. Summary of Residue Decline of Azoxystrobin and its Metabolite R230310 in Potato Tubers.

Analyte	Storage Time (days)	Trial ID 19		Trial ON 14		Trial WA 32	
		Residues (ppm)	Mean Residues (ppm)	Residues (ppm)	Mean Residues (ppm)	Residues (ppm)	Mean Residues (ppm)
Azoxystrobin	0	4.15, 3.42	3.79	3.50, 3.66	3.58	2.26, 2.17	2.22
	13-14	-	--	4.75, 4.51	4.63	2.52, 1.60	2.06
	30-32	1.51, 1.46	1.49	4.17, 4.14	4.16	2.58, 1.62	2.10
	59-61		--	4.34, 4.25	4.30	1.51, 1.39	1.45
	231	0.752, 0.435	0.594	--	--	-	--
R230310	0	<0.01, <0.01	<0.01	<0.01, <0.01	<0.01	<0.01, <0.01	<0.01
	13-14	--	--	<0.01, <0.01	<0.01	<0.01, <0.01	<0.01
	30-32	<0.01, <0.01	<0.01	<0.01, <0.01	<0.01	<0.01, <0.01	<0.01
	59-61	--	--	<0.01, <0.01	<0.01	<0.01, <0.01	<0.01

TABLE C.5. Summary of Residue Decline of Azoxystrobin and its Metabolite R230310 in Potato Tubers.

Analyte	Storage Time (days)	Trial ID 19		Trial ON 14		Trial WA 32	
		Residues (ppm)	Mean Residues (ppm)	Residues (ppm)	Mean Residues (ppm)	Residues (ppm)	Mean Residues (ppm)
	231	<0.01, <0.01	<0.01	--	--	--	--

D. CONCLUSION

The supervised residue trials on potato are considered scientifically acceptable. Based on the study results, residues of azoxystrobin may be up to 4.15 ppm (per trial average maximum of 3.79 ppm) in/on potato collected at 0 DAA following post-harvest spray application of azoxystrobin, formulated as a 2.09 lb ai/gal (250 g a.i./L) SC, at a total rate of 0.0089-0.0099 lb ai/2000 lb potatoes (4.0309-4.5105 g a.i./2000 lb potatoes [0.44-0.50 g a.i./100 kg potatoes); maximum residues of metabolite R230310 in potatoes were <0.01 ppm. Samples were analyzed for azoxystrobin and the metabolite R230310 using acceptable methods. The study is supported by adequate storage stability data for azoxystrobin and R230310.

E. REFERENCES

DP#s: 283588 and 287062
Subject: PP#9F06058 and ID#s 000100-01098 and 000100-01093. Azoxystrobin. Condition-of-Registration Data, Including Bridging Data from the 50 WDG Formulation to the 2.08 FlC Formulation on Spinach, Garden Beet, Green Onion and Celery; Storage Stability Data; and Limited Field Rotational Crop Data.
From: N. Dodd
To: J. Bazuin/C. Giles-Parker
Dated: 2/6/03
MRIDs: 45640301, 45640302, 45640304-46560307, and 45738101

DP#s: 248887 and 249671
Subject: PP#7F4864. Tolerance Petition for use of Azoxystrobin on Cucurbits. PP#8F4995. Tolerance Petition for use of Azoxystrobin on Bananas, Potatoes, and Stone Fruits.
From: D. Dotson, M. Doherty, and Y. Donovan
To: C. Giles-Parker/J. Bazuin
Dated: 10/14/98
MRIDs: 44319305, 44452303, 44595105, 44595109-44595111, 44595114, 44595116, 44613501, and 44613503

DP#s:	249657 and 249668
Subject:	PP# 7F4864. Tolerance Petition for use of Azoxystrobin on Peanut Hay, Pistachios, Rice, Tree Nuts, and Wheat. PP# 8F4995. Tolerance Petition for use of Azoxystrobin on Canola.
From:	D. Dotson
To:	C. Giles-Parker/J. Bazuin
Dated:	1/25/99
MRIDs:	44319303, 44319304, 44319306-44319308, 44452303, 44595104-44595108, 44595113, 44595115 and 44613502

DP#s:	334571 and 340016
Subject:	Azoxystrobin. Petitions for the Establishment of Permanent Tolerances for New/Amended Uses on Non-grass Animal Feeds (Crop Group 18), Sorghum, Wheat, Cotton and Wild Rice. PP#s 6F7106 & 7F7198. Summary of Analytical Chemistry and Residue Data.
From:	W. Cutchin
To:	S. Piper and T. Kish/J. Bazuin
Dated:	3/12/08
MRIDs:	46924301-46924303, 47096401-47096402

PMRA # 2044022. Chaggar, S., Crook, S.J., Harron, E.A., Robinson, N.J. (2006) "RAM 305/03: Residue Analytical Method for the Determination of Residues of Azoxystrobin (ICI5504) and R230310 in Crop Samples. Final Determination by LC-MS/MS. Unpublished study prepared by Syngenta, Berkshire, UK. 65 pages.

PMRA # 956496. Gill, J.P., and Burke, S.R. (2002) "Azoxystrobin Stability in Crops and Processed Commodities During Frozen Storage (Final Report)". Laboratory Project ID: AZOX-99-SS-01. Unpublished study prepared by Syngenta, Berkshire, UK. 84 pages.

PMRA # 1191031. Burke, S.R. (1997) "Azoxystrobin and R230310: Storage Stability in Various Crops Stored Deep Frozen for up to Two Years. Final Report." Report Series RJ2404B. Unpublished study prepared by Zeneca Agrochemicals. Bracknell Berkshire, UK. 45 pages.

F. DOCUMENT TRACKING

RDI: M. Negussie (08-04-2011); ChemTeam (08-17-2011); L. Cheng (01-05-2012)
Petition Number: PP#1E7851
DP Barcode: 390152
PC Code: 128810

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Primary Evaluator	Meheret Negussie, Chemist Risk Assessment Branch III Health Effects Division (7509P) Meheret Negussie	Date: 01/04/2012
Peer Reviewer	Melissa Watchorn, Evaluation Officer Minor Use Assessment Section (MUAS) Health Evaluation Directorate (HED) Pest Management Regulatory Agency (PMRA)	Date: Jan 6, 2012
Approved by	Jennifer Selwyn, Section Head Minor Use Assessment Section (MUAS) Health Evaluation Directorate (HED) Pest Management Regulatory Agency (PMRA)	Date: Jan 13/2012
Approved by	Leung Cheng, Senior Chemist Risk Assessment Branch III Health Effects Division (7509P) Leung Cheng	Date: 01/05/2012

This DER was originally prepared under contract by Versar, Inc. (6850 Versar Center, Springfield, VA 22151; submitted (7/22/2011). The DER has been reviewed by HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORTS:

MRID No. 48437101. PMRA No. 2044028. Hampton, M. (2011) Azoxystrobin + Fludioxonil + Difenoconazole: Magnitude of the Residue on Potato Following Post-Harvest Treatment: Final Report. Report Number: IR-4 PR No. 09860 and TK0003297. Unpublished study prepared by Syngenta Crop Protection, Inc. 1011 p.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. submitted a processing study for difenoconazole, azoxystrobin, and fludioxonil on potato following post-harvest treatment. This DER pertains to the magnitude of residues of azoxystrobin and the Z-isomer metabolite R230310 only; difenoconazole and fludioxonil results are reported in separate DERs. One post-harvest trial was conducted in Kimberley, ID, in 2009. Potatoes were grown on-site by the trial personnel and mature potato tubers were harvested, placed in on-site storage for ~2 months, and then treated with a spray mixture containing a 3.00 lb ai/gal (360 g a.i./L) difenoconazole flowable suspension (FS) formulation, a 2.09 lb ai/gal (250 g a.i./L) azoxystrobin soluble concentrate (SC) formulation, and a 1.92 lb ai/gal (230 g a.i./L) fludioxonil SC formulation. The test mixture was applied as a post-harvest treatment spray directed to tubers falling from a conveyor belt at 1X the application rate of 0.0091 lb azoxystrobin/2000 lb potatoes (4.1357 g azoxystrobin/2000 lb potatoes [0.46 g a.i./100 kg potatoes]) using water as the carrier. The delivery rate was 0.51 gal/2000 lb potatoes (0.21 L/100 kg potatoes). Potato samples were collected after the spray had dried on the day of application [0 days after application (DAA)] and processed into flakes, chips, and wet peel by the University of Idaho Food Technology Center (Caldwell, ID) using simulated commercial procedures. Adequate descriptions were provided of the processing procedures, including material balance summaries.

Potato raw agricultural commodity (RAC) and processed fraction samples were analyzed for residues of azoxystrobin and its metabolite R230310 using modified Syngenta Method RAM 305/03 (MRID 47096401; PMRA # 2044022), a high pressure liquid chromatography/tandem mass spectrometry (LC/MS/MS) method. This method has been reviewed previously and deemed acceptable for data gathering. The limit of quantitation (LOQ; determined as the lowest limit of method validation, LLMV) was 0.01 ppm for azoxystrobin and R230310 in all potato matrices. The method was verified prior to and in conjunction with sample analysis and is considered adequate based on acceptable method validation and concurrent recovery data. The fortification levels used in method validation and concurrent method recovery were adequate to bracket expected residue levels.

The maximum storage durations of samples from collection/processing to analysis were 140 days (4.6 months) for potato (RAC), 209 days (6.9 months) for flakes, 222 days (7.3 months) for chips, and 166 days (5.5 months) for wet peel. Analysis took place between 0 and 3 days after extraction. Adequate storage stability data are available indicating that residues of azoxystrobin and R230310 are stable at <-15 °C for at least 24 months in/on soybean meal, corn grits, carrot root, leaf lettuce, grain sorghum forage, orange oil, and orange juice (MRID 45738101; PMRA # 956496). Additionally, data on file indicate residues of azoxystobin and R230310 are stable for up to 2 years in cucumbers, apples, grapes, peaches, peanuts, pecans, rapeseed, tomatoes, bananas, and wheat grain (MRID 44452303; PMRA # 1191031). According to the OECD Guidelines for the Testing of Chemicals (Test No. 506, Adopted 16 October, 2007), if there is no observed decline of residues across the range of five different commodity categories (high water content, high oil content, high protein content, high starch content, and high acid content), then residues are stable in all commodities, and specific freezer storage stability data for processed foods are not needed. Therefore there are no concerns regarding the stability of azoxystrobin and R230310 residues in any samples in this study.

Concentration of residues in potatoes treated with one post-harvest treatment of azoxystrobin (4.1357 g azoxystrobin/2000 lb potatoes [0.46 g a.i./100 kg potatoes]) following processing was not observed in potato processed fractions. Mean residues of azoxystrobin were 0.938 ppm for potato tuber (RAC), <0.01 ppm for flakes, 0.0111 ppm for chips (resulting in a processing factor of 0.01x), and 0.846 ppm for wet peel (resulting in a processing factor of 0.90x). Residues of metabolite R230310 were below the LOQ (<0.01 ppm) in/on all samples of potato RAC, flakes, chips, and wet peel. Therefore, no processing factors were calculated for R230310. All of the processing factors calculated in this study were less than the maximum theoretical concentration factors of 4.7x for dried potatoes (flakes and granules) and 4.0x for processed waste (based on loss of water and separation of components; OPPTS 860.1520, Tables 2 and 3; DIR98-02, Section 10).

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP# 390152, and in Canada's forthcoming Evaluation Report.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance, and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Azoxystrobin is a broad spectrum fungicide for control of many plant diseases. It has the same biochemical mode of action as the naturally occurring strobilurins and is structurally related to them. Azoxystrobin is a ß-methoxyacrylate. It is in the same chemical class as trifloxystrobin. Azoxystrobin acts by inhibiting electron transport.

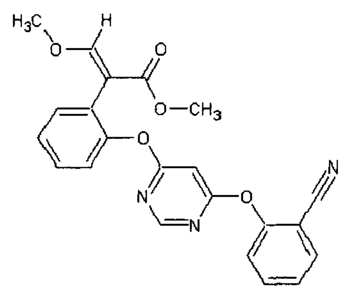
TABLE A.1. Test Compound Nomenclature.	
Compound	Chemical Structure 
Common name	Azoxystrobin
Company experimental name	ICIA5504
IUPAC name	methyl (2*E*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
CAS name	methyl (*αE*)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-α-(methoxymethylene)-benzeneacetate
CAS #	131860-33-8
End-use product/(EP)	Azoxystrobin SC is a suspension concentrate formulation containing 2.09 lb ai/gal (250 g a.i./L) azoxystrobin (Azoxystrobin 250 SC).

TABLE A.2. Physicochemical Properties of the Technical Grade Azoxystrobin.		
Parameter	Value	Reference[1]
Melting point/range	114-116° C	43678105
pH	6.4	43678105

TABLE A.2. Physicochemical Properties of the Technical Grade Azoxystrobin.		
Parameter	Value	Reference[1]
Density	1.25 g/cm^3	43678105
Water solubility (mg/L at 20°C)	solvent / solubility water, pH 5.2: 6.7 mg/L water, pH 7: 6.7 mg/L water, pH 9.2: 5.9 mg/L	43678105
Solvent solubility (mg/L at 20°C)	solvent / solubility n-hexane: 0.057 mg/mL methanol: 20 mg/mL ethyl acetate: 130 mg/mL toluene: 55 mg/mL acetone: 86 mg/mL dichloromethane: 400 mg/mL	43678105
Vapor pressure at 25°C	1.1 x 10^{-13} kPa = 8.2 x 10^{-13} mg Hg	43678105
Dissociation constant (pK_a)	Not dissociable	43678105
Octanol/water partition coefficient Log(K_{OW})	log P_{0w} = 2.5	43678105
UV/visible absorption spectrum	Not available	

[1]DP#s 218318 and 218448, 3/19/96, J. Garbus

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

A post-harvest field trial was conducted in Kimberley, ID. Potatoes were grown on-site by the trial personnel and mature potato tubers were harvested and placed in on-site storage for ~2 months. Azoxystrobin was applied as a post-harvest treatment spray directed to tubers falling from a conveyor belt at 1X the application rate of 0.0091 lb ai/2000 lb potatoes (4.1357 g ai/2000 lb potatoes [0.46 kg a.i./100 kg potatoes]) using water as the carrier. The delivery rate was 0.51 gal/2000 lb potatoes (0.21 L/100 kg potatoes). Potato samples were collected after the spray had dried (0 DAA), stored at ambient conditions overnight, and transported to the processing facility the following day. The actual trial use patterns are reported in Table B.1.

TABLE B.1. Study Use Pattern.							
Location City, State; Year (Trial ID)	EP[1]	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Delivery Rate (gal/2000 lb) [L/100 kg]	RTI (days)	Total Rate		
					g a.i./ 2000 lb	lb a.i./ 2000 lb [g a.i./100 kg]	
Kimberly, ID; 2009 (09-ID19)	SC	Spray directed to tubers falling from conveyor belt; Post-harvest	0.51 [0.21]	-	4.1357	0.0091 [0.46]	-

[1] EP = End-use Product; suspension concentrate (SC) formulation containing 2.09 lb azoxystrobin/gal (250 g azoxystrobin/L).

B.2. Sample Handling and Processing Procedures

Composite bulk samples of untreated and treated potatoes (250 lb [114 kg]) were collected and shipped at ambient temperature within 1 day to the University of Idaho Food Technology Center

(Caldwell, ID). Samples were placed in storage (4 ± 3 °C) prior to processing. Processing was initiated within 7 days of harvest. The processing procedure simulated commercial operations of potato production as closely as possible to generate the required fraction of potato tuber (RAC), flakes, chips, and wet peel, with some variations to commercial methods. The processed fractions were stored frozen at -17 ±8 °C at the processing facility. Processing flowcharts for potato, copied without alteration from MRID 48437101, are presented below in Figures 1.1 and 1.2.

After processing, samples were shipped frozen to Syngenta Crop Protection (Greensboro, NC) for preparation and analysis. At the analytical laboratory, samples were stored in temperature-monitored freezers at -20 ± 5 °C until preparation/analysis. In preparation for analysis, the potato (RAC), chip, and wet peel samples were ground with dry ice in a Hobart food grinder equipped with a 1/8 inch plate or a Robot Coupe Vertical Cutter (RAC samples only) to a homogeneous consistency and then returned to frozen storage until extraction. No additional processing was needed for the potato flake samples.

FIGURE 1.1. Processing Flowchart for Potato (Wet Peel and Flakes)

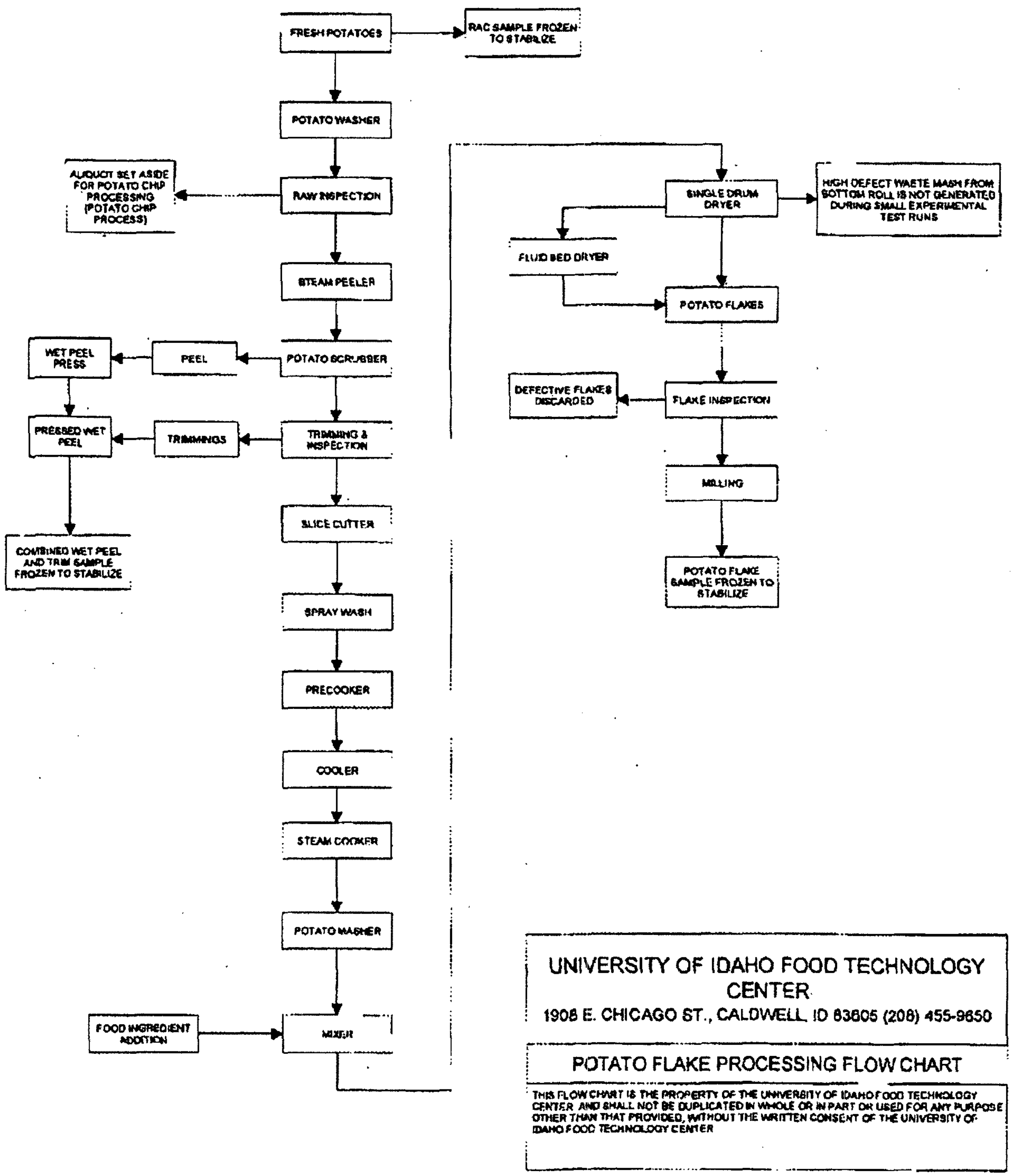
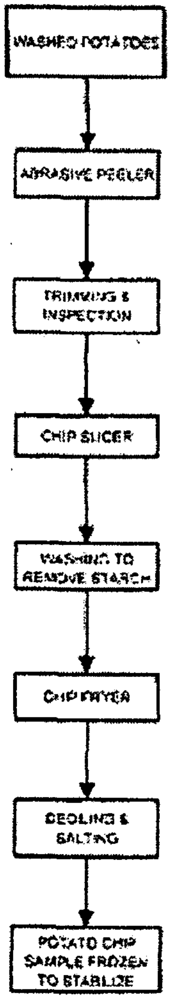


FIGURE 1.2. Processing Flowchart for Potato (Chip)



UNIVERSITY OF IDAHO FOOD TECHNOLOGY CENTER
1908 E. CHICAGO STREET., CALDWELL, ID 83605 (208 455-8650

POTATO CHIP PROCESSING FLOW CHART

B.3. Analytical Methodology

Samples of potato (RAC) and its processed fractions (flakes, chips, and wet peel) were analyzed for residues of azoxystrobin and its metabolite R230310 using a LC-MS/MS method modified from Syngenta Analytical Method RAM 305/03 (MRID 47096401; PMRA # 2044022). The method has been reviewed previously and deemed acceptable for data gathering. The modifications to the reference method were minor, and did not include changes to extraction solvents, cleanup procedures, or quantitation methods. A brief description of the method was included in the submission.

Residues of azoxystrobin and R230310 in potato RAC and processed fraction samples were extracted with acetonitrile/water (90:10, v:v) and centrifuged. Aliquots of the extracts were cleaned up using solid phase extraction and analyzed using LC-MS/MS detection.

The LOQ (determined as the LLMV) was 0.01 ppm for each analyte in all matrices; the limit of detection (LOD) was not reported.

The method was validated prior to and in conjunction with the field trial samples.

C. RESULTS AND DISCUSSION

One post-harvest trial was conducted on potatoes in the US in 2009. Potatoes were treated with one spray application directed to the tubers at a rate of 0.46 g azoxystrobin/100 kg potatoes. Samples were stored at ambient temperatures overnight, and were then sent to a processing facility where they were processed into flakes, chips, and wet peel simulating commercial processing procedures.

Sample storage conditions and durations are summarized in Table C.2. After processing, samples were stored frozen (-10 °C) until analysis. The maximum storage duration of azoxystrobin and R230310 samples from collection/processing to analysis was 140 days (4.6 months) for potato (RAC), 209 days (6.9 months) for flakes, 222 days (7.3 months) for chips, and 166 days (5.5 months) for wet peel. Analysis took place between 0 and 3 days after extraction. Adequate storage stability data are available indicating that residues of azoxystrobin and R230310 are stable at <-15 °C for at least 24 months in/on soybean meal, corn grits, carrot root, leaf lettuce, grain sorghum forage, orange oil, and orange juice (MRID 45738101; PMRA # 956496). Additionally, data on file indicate residues of azoxystobin and R230310 are stable for up to 2 years in cucumbers, apples, grapes, peaches, peanuts, pecans, rapeseed, tomatoes, bananas, and wheat grain (MRID 44452303; PMRA # 1191031). According to the OECD Guidelines for the Testing of Chemicals (Test No. 506, Adopted 16 October, 2007), if there is no observed decline of residues across the range of five different commodity categories (high water content, high oil content, high protein content, high starch content, and high acid content), then residues are stable in all commodities, and specific freezer storage stability data for processed foods are not needed. Therefore there are no concerns regarding the stability of azoxystrobin and R230310 residues in any samples in this study.

Concurrent method recovery data and method validation data for the LC/MS/MS method is presented in Table C.1. For concurrent method recovery and method validation recovery, potato RAC and processed fraction samples were fortified at 0.01-10 ppm with azoxystrobin and R230310. Average recoveries were within the acceptable range of 70-120%. The method is considered adequate based on concurrent recovery and method validation data. The fortification levels used in concurrent method recovery were adequate to bracket expected residue levels.

Apparent residues of azoxystrobin and R230310 were each below the LOQ (<0.01 ppm) in/on all samples of untreated potatoes in the RAC and processed fraction samples. Additionally, there were no interferences reported in the control samples.

Residue data from the potato processing study are reported in Table C.3. Mean residues of azoxystrobin were 0.938 ppm for potato tuber (RAC), <0.01 ppm for flakes, 0.0111 ppm for chips (resulting in a processing factor of 0.01x), and 0.846 ppm for wet peel (resulting in a processing factor of 0.90x). Residues of metabolite R230310 were below the LOQ (<0.01 ppm) in/on all samples of potato RAC, flakes, chips, and wet peel. Therefore, no processing factors were calculated for R230310.

All of the processing factors calculated in this study were less than the maximum theoretical concentration factors of 4.7x for dried potatoes (flakes and granules) and 4.0x for processed waste (based on loss of water and separation of components; OPPTS 860.1520, Tables 2 and 3; DIR98-02, Section 10).

TABLE C.1. Summary of Method and Concurrent Recoveries of Azoxystrobin and its Metabolite R230310 from Potato.

Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)[1]	Mean ± Std. Dev. (%)[2]
Method Validation Recoveries					
Potato RAC	Azoxystrobin	0.01	3	98, 89, 99	95 ± 5.5
		0.1	3	116, 115, 117	116 ± 1.0
		1.0	3	72, 90, 100	87 ± 14
		10	3	73, 76, 102	84 ± 16
	R230310	0.01	3	105, 96, 114	105 ± 9.0
		0.1	3	119, 117, 120	119 ± 1.5
		1.0	3	73, 88, 95	85 ± 11
		10	3	70, 77, 102	83 ± 17
Flakes	Azoxystrobin	0.01	3	96, 94, 97	96 ± 1.5
		0.1	3	104, 105, 91	100 ± 7.8
		1.0	3	88, 98, 105	97 ± 8.5
		10	3	100, 119, 111	110 ± 10
	R230310	0.01	3	95, 92, 95	94 ± 1.7
		0.1	3	103, 102, 88	98 ± 8.4
		1.0	3	86, 98, 105	96 ± 9.6
		10	3	99, 115, 108	107 ± 8.0
Chips	Azoxystrobin	0.01	3	87, 88, 93	89 ± 3.2
		0.1	3	95, 98, 90	94 ± 4.0
		1.0	3	96, 94, 95	95 ± 1.0
		10	3	93, 90, 85	89 ± 4.0

TABLE C.1. Summary of Method and Concurrent Recoveries of Azoxystrobin and its Metabolite R230310 from Potato.

Matrix	Analyte	Spike Level (ppm)	Sample Size (n)	Recoveries (%)[1]	Mean ± Std. Dev. (%)[2]
	R230310	0.01	3	87, 78, 86	84 ± 4.9
		0.1	3	94, 95, 87	92 ± 4.4
		1.0	3	95, 96, 96	96 ± 0.6
		10	3	92, 90, 87	90 ± 2.5
Concurrent Recoveries					
Potato	Azoxystrobin	0.01	6	101, 98, 111, 107, 95, 89	100 ± 8.0
		1.0	4	94, 100, 92, 97	96 ± 3.5
		10	2	118, 87	103
	R230310	0.01	6	98, 103, 117, 99, 100, 94	102 ± 8.0
		1.0	4	96, 98, 93, 94	95 ± 2.2
		10	2	115, 89	102
Flakes	Azoxystrobin	0.01	3	83, 85, 86	85 ± 1.5
		10	1	93	93
	R230310	0.01	3	78, 87, 89	85 ± 5.9
		10	1	94	94
Chips	Azoxystrobin	0.01	3	86, 85, 84	85 ± 1.0
		10	1	96	96
	R230310	0.01	3	88, 89, 92	90 ± 2.1
		10	1	98	98
Wet peel	Azoxystrobin	0.01	6	89, 87, 93, 89, 100, 97	93 ± 5.1
		10	1	87	87
	R230310	0.01	6	88, 106, 104, 90, 97, 115	100 ± 10
		10	1	86	86

[1] The concurrent recoveries were corrected for apparent residues in the unfortified control samples.
[2] Standard deviations were calculated only for fortification levels having ≥3 samples.

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TABLE C.2. Summary of Storage Conditions.

Matrix	Analyte	Storage Temperature (°C)	Actual Storage Duration[1]	Limit of Demonstrated Storage Stability
Potato RAC	Azoxystrobin	<-10	140 days (4.6 months)	Adequate storage stability data are available indicating that residues of azoxystrobin and R230310 are stable at <-15 °C for at least two years in/on soybean meal, corn grits, carrot root, leaf lettuce, grain sorghum forage, orange oil, and orange juice.[2] Additionally, data on file indicate residues of azoxystobin and R230310 are stable for up to 2 years in cucumbers, apples, grapes, peaches, peanuts, pecans, rapeseed, tomatoes, bananas, and wheat grain (MRID 44452303; PMRA # 1191031)[3]. According to the OECD Guidelines for the Testing of Chemicals (Test No. 506, Adopted 16 October, 2007), if there is no observed decline of residues across the range of five different commodity categories (high water content, high oil content, high protein content, high starch content, and high acid content), then residues are stable in all commodities, and specific freezer storage stability data for processed foods are not needed. Therefore there are no concerns regarding the stability of azoxystrobin and R230310 residues in any samples in this study.
	R230310			
Flakes	Azoxystrobin		209 days (6.9 months)	
	R230310			
Chips	Azoxystrobin		222 days (7.3 months)	
	R230310			
Wet peel	Azoxystrobin		166 days (5.5 months)	
	R230310			

[1] Interval from collection/processing to analysis. Extracts were stored 0-3 days prior to analysis. Samples were stored 7 days before processing.
[2] Refer to DER for MRID 45738101 (DP# 287062); PMRA # 956496.
[3] Refer to DER for MRID 44452303 (DP# 248887); PMRA #1191031).

TABLE C.3. Residue Data from Potato Processing Studies with Azoxystrobin.

RAC	Proc. Comm.	Total Rate		DAA	Residues (ppm)			Processing Factor[1,2]		
		g a.i./ 2000 lb	lb a.i./ 2000 lb [g a.i./100 kg]		Azoxy. [mean]	R230310 [mean]	Total Mean Residues	Azoxy.	R230310	Total Residues
Potato	Tubers (RAC)	4.1357	0.0091 [0.46]	0	0.950, 0.925 [0.938]	<0.01, <0.01 [<0.01]	<0.948	--	--	--
	Flakes				<0.01, <0.01 [<0.01]	<0.01, <0.01 [<0.01]	<0.02	<0.01x	NC	<0.02x
	Chips				0.0113, 0.0108 [0.0111]	<0.01, <0.01 [<0.01]	<0.0211	0.01x	NC	<0.02x
	Wet peel				0.810, 0.882 [0.846]	<0.01, <0.01 [<0.01]	<0.856	0.90x	NC	<0.90x

[1] NC = Not calculated; residues were below the LOQ (<0.01 ppm for all in analytes) in the RAC and processed fraction.
[2] Processing Factor = [Measured residue for analyte in the processed fraction] / [Measured residue for analyte in the RAC].

D. CONCLUSION

The submitted potato processing study is considered scientifically acceptable. Processing of the tuber RAC with quantifiable residues of azoxystrobin did not result in the concentration of residues in potato fractions (processing factors were all <1x). Residues of R230310 were below the LOQ in/on all samples of potato RAC, flakes, chips, and wet peel. Therefore, processing factors were not calculated for R230310. The observed concentration factors were less than the theoretical concentration factors.

Acceptable methods were used for the determination of residues of azoxystrobin and the Z-isomer metabolite. The sample storage conditions and durations for azoxystrobin analyses are supported by adequate storage stability data.

E. REFERENCES

DP#s: 283588 and 287062
Subject: PP#9F06058 and ID#s 000100-01098 and 000100-01093. Azoxystrobin. Condition-of-Registration Data, Including Bridging Data from the 50 WDG Formulation to the 2.08 FlC Formulation on Spinach, Garden Beet, Green Onion and Celery; Storage Stability Data; and Limited Field Rotational Crop Data.
From: N. Dodd
To: J. Bazuin/C. Giles-Parker
Dated: 2/6/03
MRIDs: 45640301, 45640302, 45640304-46560307, and 45738101

DP#s:	248887 and 249671
Subject:	PP#7F4864. Tolerance Petition for use of Azoxystrobin on Cucurbits. PP#8F4995. Tolerance Petition for use of Azoxystrobin on Bananas, Potatoes, and Stone Fruits.
From:	D. Dotson, M. Doherty, and Y. Donovan
To:	C. Giles-Parker/J. Bazuin
Dated:	10/14/98
MRIDs:	44319305, 44452303, 44595105, 44595109-44595111, 44595114, 44595116, 44613501, and 44613503

DP#s:	249657 and 249668
Subject:	PP# 7F4864. Tolerance Petition for use of Azoxystrobin on Peanut Hay, Pistachios, Rice, Tree Nuts, and Wheat. PP# 8F4995. Tolerance Petition for use of Azoxystrobin on Canola.
From:	D. Dotson
To:	C. Giles-Parker/J. Bazuin
Dated:	1/25/99
MRIDs:	44319303, 44319304, 44319306-44319308, 44452303, 44595104-44595108, 44595113, 44595115 and 44613502

DP#s:	334571 and 340016
Subject:	Azoxystrobin. Petitions for the Establishment of Permanent Tolerances for New/Amended Uses on Non-grass Animal Feeds (Crop Group 18), Sorghum, Wheat, Cotton and Wild Rice. PP#s 6F7106 & 7F7198. Summary of Analytical Chemistry and Residue Data.
From:	W. Cutchin
To:	S. Piper and T. Kish/J. Bazuin
Dated:	3/12/08
MRIDs:	46924301-46924303, 47096401-47096402

PMRA # 2044022. Chaggar, S., Crook, S.J., Harron, E.A., Robinson, N.J. (2006) "RAM 305/03: Residue Analytical Method for the Determination of Residues of Azoxystrobin (ICI5504) and R230310 in Crop Samples. Final Determination by LC-MS/MS. Unpublished study prepared by Syngenta, Berkshire, UK. 65 pages.

PMRA # 956496. Gill, J.P., and Burke, S.R. (2002) "Azoxystrobin Stability in Crops and Processed Commodities During Frozen Storage (Final Report)". Laboratory Project ID: AZOX-99-SS-01. Unpublished study prepared by Syngenta, Berkshire, UK. 84 pages.

PMRA # 1191031. Burke, S.R. (1997) "Azoxystrobin and R230310: Storage Stability in Various Crops Stored Deep Frozen for up to Two Years. Final Report." Report Series RJ2404B. Unpublished study prepared by Zeneca Agrochemicals. Bracknell Berkshire, UK. 45 pages.

F. DOCUMENT TRACKING

RDI: (M. Negussie; 08-04-2011); ChemTeam (08-17-2011); L. Cheng (01-05-2012)
Petition Number: PP#1E7851
DP Barcode: 390152
PC Code: 128810

Template Version June 2005

13544

R168558

Chemical Name:	Atrazine
PC Code:	080803
HED File Code:	61500 SRRD Risks
Memo Date:	8/15/2000
File ID:	00000000
Accession #:	412-10-0004

HED Records Reference Center
1/5/2012